A

OPP-20030252-

Transcript of

Registration Review Work Group Meeting

Pesticide Program Dialogue Committee

Sheraton Crystal City Hotel

1800 Jefferson Davis Highway

Arlington, Virginia

July 16, 2003

For The Record, Inc.
Waldorf, Maryland
(301)870-8025

ATTENDANCE LIST

Jay Ellenberger	Acting Director, Field and External Affairs Division
Betty Shackleford	Acting Director, Special Review and Reregistration Division
Jim Jones	Office of Pesticide Programs
Anne Lindsay	Office of Pesticide Programs
Dan Botts	PPDC

ROSTER -- PPDC Registration Review Workgroup

(Not all members present)

Britt Bailey	Center for Ethics and Toxics
Cindy Baker	Gowan Company
Carolyn Brickey	National Campaign for Pesticide Policy Reform
Patti Bright	American Bird Conservancy
Sue Crescenzi	Steptoe & Johnson, LLP
Larry Elworth	Ag Partnerships
Wally Ewart	California Citrus Quality Council
Ted Head	NuFarm Americas Inc.
Steve Kellner	CSPA
Gary Libman	Emerald BioAgriculture Corp.

ATTENDANCE LIST (cont'd)

Lori McKinnon	Yurok Tribe
Therese Murtagh	USDA
Peg Perreault	EPA Region 8
Pat Quinn	The Accord Group
Bob Rosenberg	National Pest Management Association
Steve Rutz	Florida State Government
Troy Seidel	People for the Ethical Treatment of Animals
Julie Spagnoli	Bayer CropScience
Robin Spitko	New England Fruit Consultants
Warren Stickle	CPDA
Jay Vroom	CropLife American
George Wichterman	Lee County Mosquito Control District
Erik Olson (invited)	NRDC

PROCEEDINGS

- - - - -

MR. ELLENBERGER: I'd like to welcome everybody to the Registration Review Work Group Meeting today. It looks like there's a few more people that will be coming in. But I'd like to not delay any further and get started.

Betty Shackleford and I, Jay Ellenberger, will be facilitating this today and it is your meeting, that is, EPA is looking forward to a very interesting and robust dialogue about lessons learned from reregistration and tolerance reassessment, as well as moving forward in the new Registration Review Program.

But before we get into the meat of the issues and the major part of the day, there's a few things that a number of us would like to say to sort of open this up. First of all, just a reminder, this is a public meeting. It is being audiotaped and there will be transcripts sometimes in the hopefully not too distant future, but we'll let everyone know approximately when that will be, as soon as we know. But we will -- Betty and I and others here will be taking minutes throughout the day --

taking notes and do our best to get out our own minutes to all of you, hopefully, within the next week or two, so we can move forward preparing for the next meeting.

So, it is a public meeting and keep that in mind, and we welcome everybody who has come for the -- as part of the work group today as well as people in the audience. And everybody will have an opportunity throughout the day to provide input to this important issue.

Jim Jones and Anne Lindsay are here from Pesticide Programs and I know they want to make some opening remarks. So, I'll turn it over to Jim.

MR. JONES: Thanks, Jay. I'm only going to be here just for a few minutes, actually, but I wanted to personally express my thanks to all of you for agreeing to participate in this activity, which we see in the Office of Pesticide Programs, as one of the major challenges -- programmatic challenges that we're going to face in the coming years.

Participatory government, as you all know as being members of our Dialogue Committee, isn't easy and it comes with -- although the concept is a great one,

it's very hard in practice to actually pull off. And I think it's -- although it's hard for government sometimes, I think it's hardest for the stakeholders to participate. And I think your willingness to take the time and bring your expertise and knowledge to the government will help us in the long term build a better, more sustainable program that will serve all of our stakeholders.

I think that what you have chosen to do around this issue is a case in point. This is not going to be a simple program to give us advice on. There are going to be a number of challenges that we haven't even identified as issues that we'll all need to grapple with. But I'm convinced that this is the manner in which we need to in EPA, in the Office of Pesticide Programs, in particular, do our work. And that is to get the advice of the stakeholders who are most affected by our program choices here before we get too far down the road in designing programs such as this. And I think, actually, you'll see the following approach is similar to this. I don't think we'll necessarily have a PPDC work group, but getting stakeholder input prior to actually formulating

positions.

Although we will ultimately go through EPA rule-making as required by law here, I have, over the years, found that that isn't necessarily the optimal way to understand issues and to get input into an issue before the government actually takes its position, otherwise known as the proposed rule-making process.

I think that we do better when we've heard from people beforehand. So, what we're looking for here is some advice. Ideally, there will be a fair amount of consensus around many aspects of this program, but I expect that there won't always be consensus. But frankly, understanding the nature and the dynamic of the lack of consensus where it exists helps us as we go forward.

We, meaning this work group, have identified, I understand, three key issues that you are going to be focusing on. I fully expect that over the coming -- potentially today and subsequent meetings, you will identify additional issues and we are going to be willing to sort of engage on those as well.

So, I'm confident that this approach is going to

serve the agency well and is going to serve the people of this country well and will, therefore, by definition, serve the stakeholders well. We are committed to this as an approach to getting our arms around registration review. So, I really just wanted to thank all of you and give you some sense as to how much the agency and the office appreciates your participation.

You're in very confident and capable hands, Betty and Jay, and I anxiously await their report at the end of the day and tomorrow, as I expect that I'll see many of you at the transition meeting. Well, I have a -- somewhat of a booked schedule, so I'm going to leave you to your work and hopefully the very productive day.

Thanks a lot.

MR. ELLENBERGER: Thanks, Jim. Anne, did you want to make some remarks as well?

MS. LINDSAY: Just, I guess, very briefly. I've been in the government for a long time and actually I don't want to make any comment about the age of anyone on this group, but I know a few of you have either actually been in government or working closely with government for almost as long as I have, and I think when you've sort of

given that extended period, you always have to ask yourself, are you really open to new things and new ways of doing business, new issues, or have you really gotten stuck in a rut?

In the last year, I've been at a number of public events where OPP has actually received compliments, not necessarily about the substance of what we were presenting or discussing with you and others, but around the process and the way in which we conduct business. I felt very fortunate to be at some of those meetings to hear those compliments because in the 20-plus years I've been in government, I don't think I've ever heard compliments like that before.

So, obviously, it both went to our heads -- it certainly went to my head because I remember it and I'm telling you about it. But I think one of the things that actually getting those compliments did was it made me go back and think harder about public participation and the value of it and what we've actually learned from, I think, the implementation with the Quality Protection Act about public participation and it certainly made me look at the PPDC itself in a different way.

I actually think in the last year or so the PPDC has become, I think, almost the best advisory committee I've ever seen, which is not to say that the CARAT isn't a great advisory committee. But the scope of the PPDC is very, very broad and diverse and, to me, it's really cooking. A sign of it is sort of how many of the PPDC members actually held up their hand to be part of this group and to actually really do work.

When I came to the agency, we just finished our original registration regulations, so I know we didn't use a process like this. I think we had a lawyer who went in a room and wrote them. We put it out for official comment, we got comment and then we finalized it and away we went. And here we are, you know, 25 or 30 years later. I'm sure that there was some discussion that was going on and it wasn't totally a locked room, but I think it was probably close to that approach, you know. Government goes into locked room, writes something, puts it out, listens to what you have to say, maybe, finalizes it because we're always good at responding to comments. That doesn't mean we actually listen.

So, this is a really new mode of business and I'm hoping -- I think this is a first for OPP in terms of how we work on regulations and the design of important programs and activities. So, you've got a big responsibility, but -- in helping us do that and make this sort of a successful model for a way of doing business. But I'm not worried about that because you're all so good. I think Betty and Jay are going to be great co-chairs of this group and they'll have a fantastic report to give to the PPDC in October.

So, I just wanted to congratulate you on taking on the job.

MR. ELLENBERGER: Thanks, Anne. Okay. What I'd like us to do is go around the room and identify ourselves and our affiliations to get a little bit more comfortable about this organization. Again, I want to -- before we do that, I do want to thank each of you for rearranging schedules and making time out of your busy schedules to participate in this. I know that we had our first meeting, a teleconference, a couple weeks ago. Things got off to a very interesting start with the call-in number.

(Laughter.)

MR. ELLENBERGER: So, Margie is still investigating how that happened. So, there will probably be a government block on our phone lines so it won't happen again. So, to avoid that, we wanted to have a face-to-face meeting.

But in all seriousness, I appreciate everybody coming today. I know many of you are here for CARAT tomorrow and Friday. But, nevertheless, everyone has busy schedules. I appreciate that. This is very important for the agency and I think it's a very significant issue for PPDC. And so, I know that we look forward to working through the issues that we've identified this summer for your recommendations that we'll give to the next PPDC meeting at the end of October.

So, I'm Jay Ellenberger. I'm the Acting Director of the Field and External Affairs Division, Office of Pesticide Programs, and one of the co-leads for this work group.

Betty?

MS. SHACKLEFORD: Okay, I'm Betty Shackleford.

I am the Acting Director of the Special Review and Reregistration Division and our job is to keep you confused about where we all sit.

One of the things I've noticed is that we're already behind schedule, but I did want to take a minute because, while I know most of you, I really don't know most of you and I wanted you to get a little bit of an appreciation for me as I hope to be able to get an appreciation for you.

While I, like Anne, have had a lot of years in government, it's not been in EPA. I've been at a bunch of agencies, I've been in industry. I actually had to comply with environmental regulations in one of my previous positions where I was responsible for environment compliance for waste management at the Department of Energy. So, I can appreciate what it means to face the onerous task of trying to get your programs in alignment with regulations that, in many instances, you think are just totally untenable.

So, from my perspective, an opportunity to be a part of this group's effort to actually frame a program that will sort of set out how the Pesticide Office is

going to operate at least for the foreseeable future is really a very, very exciting opportunity.

So, I just wanted to tell you it's my pleasure to be here, to be able to work with you. I view our jobs as working for you. If something is happening and you're not pleased with the way it's going, if you'd like us to make an adjustment -- I tend to follow the schedule, if that's not workable for you, just say so. Because, again, we are here to facilitate this process for you. So, do not hesitate -- and I know you won't -- but do not hesitate to say, let's make some adjustments because we think things would, perhaps, be a little more effective if we proceeded in a slightly different manner.

I think what we're all interested in is hopefully getting results out of this that will be results that the agency can sort of take to the bank, if you will. So, anything that we can do to make the process more efficient for you, please, by all means, let us know.

MR. SEIDEL: Good morning, I'm Troy Seidel. I'm with PETA, People for the Ethical Treatment of Animals. And I guess I have a -- perhaps a more narrow interest in

this particular group than some of the other stakeholders where our issue, of course, is animal testing in EPA's Pesticide Program and how we can minimize that to the extent possible.

So, in the context of reregistration review where new data is required, we'd like to be able to insert some broad consideration of how to minimize animal testing into the overall process. So, I'm happy to be part of that discussion early on. Thank you.

MS. SPITKO: My name is Robin Spitko. I'm an independent crop consultant. I've been doing integrated pest management in New England working with tree fruit growers for the last 20 years. And we're very interested in the EUP process. Being a heavily OP dependent group, we'd like to see changes and be more informed on how that process works as part of the registration process. Thank you.

MR. VROOM: I'm Jay Vroom, President of CropLife America.

MS. BRIGHT: I'm Patti Bright. I'm playing a dual role today. I'm an American Bird Conservancy veterinarian and also a representative for the National

Pesticide Coalition, which for those of you who don't know what that is, it's a group of about -- currently, there's about 20 organizations that belong. We represent interests in public health, animal health and environmental health.

MR. KELLNER: I'm Steve Kellner with Consumer Specialty Products Association. We represent the non-agriculture aspects of the industry. We're, obviously, concerned with registration issues. I've been around here a long time, also. I think going back to my first meeting with EPA I was 12 years old.

(Laughter.)

MR. KELLNER: Just kidding, of course. Sometimes it seems that way.

UNIDENTIFIED MALE: I think you and I met.

(Laughter.)

MR. HEAD: I'm Ted Head with NuFarm Americas, Incorporated. I am responsible for product registration. So, the outcome of these talks will have a direct impact not only upon the work I do for NuFarm but on the bottom line for NuFarm as well.

MS. CRESCENZI: I'm Sue Crescenzi, Steptoe &

Johnson, here for the American Chemistry Council Biocides Panel, and the panel represents numerous registrants of various types of anti-microbials, wood preservatives, and anathalons (phonetic). It's a very broad spectrum. So, obviously, all of these issues are of very significant importance.

MR. BOTTS: I'm Dan Botts, a member of PPDC and not officially a member of this work group, but just because I didn't get my hand up in time to request to be on the list to begin with and missed a conference call because of other issues like methyl bromide and critical use nomination package being reviewed at the international level, which has tied up the last three weeks pretty tightly.

But just as a general perspective -- and I think Anne and I probably started about the same time in this process -- I would echo some of the compliments that EPA has gotten over FQPA implementation. The transparency in this agency and the ability to put issues before this agency is probably at a level that's never been precedented in the history of working with pesticides going back to the late '70s, early '80s. It's made a

better process.

Reregistration, whether it was ARPAR (phonetic) or FIFRA Light (phonetic) or FQPA Tolerance Reassessment, has been an integral process that has been extremely complicated as you take older products that are out there in the workplace and try to come up with standards or qualifications on looking at their history of use. It's a different process, in my opinion, than a new product registration because of that probably has different data needs, different data requirements and different issues surface.

One of the things that's critically important to my industry, because it is a fresh product industry, is having a process that works, that everybody understands and everybody believes in, no matter which side of the table you sit on. This process, as we go forward, will be just as important as the reregistration process was earlier and it's critically important to my industry.

So, even though I'm not an official member of the work group, I'm going to be looking over your shoulders.

MS. BAKER: Cindy Baker with Gowan Company. I'm

short.

(Laughter.)

MR. STICKLE: I'm Warren Stickle with the Chemical Producers and Distributors Association.

MS. SPAGNOLI: Julie Spagnoli, Bayer Health Care's Animal Health Division representing animal use pesticides, but I've also -- this is probably one of the few segments of -- a new segment of FIFRA products, but I've had previous experience in household insecticides, DEET repellants, lawn and garden, termiticides crop protection, chemicals. So, I basically have dealt with almost every aspect as a formulator, as a basic and so, I hope to bring that wide range of experience and good things and bad things that I've encountered over the years and use that in this process.

MR. WICHTERMAN: I'm George Wichterman, Entomologist with the Lee County Mosquito Control District and I can identify with what Anne Lindsay had to say a while ago about long-term employees. I've been with the District now a little over 31 years as their entomologist. So, I can relate to what you said.

We're, obviously, interested in public health

vector control programs and what happens with the pesticides that we currently have in our inventory, we do not have any new chemistry, so we have to rely on what is already currently there. So, we have to preserve and protect what we have. So, that's our interest here at the table.

MR. ROSENBERG: I'm Bob Rosenberg. I represent the National Pest Management Association and I'm one of the other old people that Anne was referring to, but not as old as Steve or Dan.

(Laughter.)

MR. ROSENBERG: The people I represent, they're a 6,000-member company, Structural Pest Control Operators, that use a wide array of products for non-agricultural uses and we have a fairly significant interest in this process and ensuring the availability of products for the folks that we represent.

MS. MURTAGH: I'm Therese Murtagh. I'm with the USDA Office of Pest Management Policy and the Department is very interested in this process and we work in great partnership with EPA and with many of you throughout FQPA implementation. I think that working together we did do

a very good job of defining a process. Sometimes it was difficult. It will probably continue to be, you know, but it's a good process and I am hoping that this group will be able to design a process that will work as well as the FQPA Reregistration Tolerance Reassessment Process.

MR. ELLENBERGER: Thanks. I'd like the people in the audience to also identify themselves.

UNIDENTIFIED MALE: (Inaudible).

MR. McALLISTER: Ray McAllister with CropLife America.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: (Inaudible).

MR. SIEFERT: David Siefert (phonetic), Bureau of National Affairs.

UNIDENTIFIED FEMALE: Mary Beth (inaudible).

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: (Inaudible).

MR. HERNANDEZ: Frank Hernandez, EPA, Office of

Pesticides, Economic Analysis Division.

MR. ELLENBERGER: Thank you. I'd like to point your attention to the folder that you've had in front of you. This is material that we'll use today. For those of you in the public seating area, there were copies of this on the front table.

You'll see a copy of the agenda and the minutes from our first meeting, our teleconference meeting; also a copy of the mission statement, FIFRA Section 3G that is the reason that we're sitting in this room today talking about registration review; and also behind that is a copy of the registration review presentation that the agency gave to the last full PPDC meeting; and then lastly -- it should be somewhere on the left or elsewhere, but it's a copy of the workgroup members. If there are any errors in the names, name spellings or affiliations, phone numbers, email addresses, let me know or let Betty know and we'll correct that for the future.

So, moving forward on today's agenda is a review of the minutes from the first meeting. It's one page. We tried to keep it really short and to the point and hopefully some of you had a chance to look at this after

we sent it out, after Margie sent it out a couple weeks ago on email. I'm certainly not going to read it, but this was really the meeting to focus on -- focus this work group on what we wanted to accomplish through this series of meetings this summer leading up to the October PPDC meeting at the end of October. And we talked a little bit about background and purpose of the work group.

The mission statement that you all have is also in today's folder. I know we had a brief discussion on the scope of registration review. We'll get into that in a few minutes and then try and take a look at or try and narrow down the issues that this work group will talk about.

As Jim Jones mentioned this morning, there are lots of pieces of the process for registration review, just like there has been for the reregistration and tolerance reassessment, and in the relatively short amount of time that we have, we certainly can't get into every step of the process. So, I'm trying to figure out what are big, important components of the process for registration review, what do we think we can

realistically have constructive dialogue on in four or so meetings so that we can -- so that you all can make recommendations to PPDC in October.

So, we really focused our attention on sort of a priority scheduling system for all the chemicals for registration review and what are the thoughts behind that, considerations for different levels, perhaps different levels of the review for different pesticide chemicals and then stakeholder involvement in the registration review process.

Any comments, discussions about the minutes?

(No response.)

MR. ELLENBERGER: I guess we did an okay job with that.

UNIDENTIFIED MALE: Could you add my name to that just for the record? I was on the call. I was late getting in because of the telephone problem.

MR. ELLENBERGER: Sure.

UNIDENTIFIED FEMALE: You stayed on the other line too long?

UNIDENTIFIED MALE: (Inaudible) I couldn't hang on.

(Laughter.)

MR. ELLENBERGER: We won't discuss which phone line you were on.

(Laughter.)

MR. ELLENBERGER: Okay, good, thank you. All right. We're actually ahead of schedule now. We want to talk about lessons learned. As Jim and Anne mentioned this morning, and a number of you going around the table, it's very important for the Pesticide Program to get feedback and input moving forward in any new process. And, certainly, as we all know in our day-to-day jobs, having lessons learned from whatever we've done in the past is really key and critical to a better job next time.

So, we want to spend a good bit of this morning going through lessons learned from the current reregistration process that's been in place for many years, as well as the tolerance reassessment process since FQPA. I think there's an awful lot, I believe, we can talk about and discuss on lessons learned. I think what I would suggest that you all do is do brainstorming and try to keep this -- try to keep the points really

succinct, you know, really to the point. And I'd also ask that -- well, think about the lessons learned particularly in light of the three major topics that we'll be discussing today and in future meetings. I think that will help us getting started on talking about those three major topics.

But I don't want to, you know, sort of constrain you just to those, but those are -- Betty and I think those are the three main -- those are the real focus of lessons learned, but feel free to add anything else to that.

Rich Dumas from our Reregistration Division is going to help capture lessons learned, so the pros and the cons, if you will, so that we can just sort of help the dialogue along.

So, with that, let me open it up to all of you. Lessons learned. Bob?

MR. ROSENBERG: Are we going to do like (inaudible) or what's our procedure (inaudible)?

MS. SHACKLEFORD: You're showing your experience, Bob.

(Laughter.)

MR. ELLENBERGER: I guess I would feel comfortable not having to keep it so formal, but obviously let's try to talk one at a time and not try to talk over one another and so on and so forth.

MR. ROSENBERG: Okay, well, that's (inaudible).

UNIDENTIFIED MALE: (Inaudible) want to add one thing to the discussion (inaudible) had a narrower focus than (inaudible). I think in the course of the tolerance reassessment process, the people -- and I know Steve maybe in particular and George, to some extent -- would feel like non-agricultural uses, oftentimes, were not supported by as much data as (inaudible) agricultural products. And I know that's probably changing and some of that data (inaudible).

I guess my one objective in all this is to try to make sure that we identify some kind of process or identify early in the process (inaudible) so that the data is available to make those decisions. I mean, some sort of (inaudible) residential data. (Inaudible) would like us to kind of figure out now what the problems are, what the data means are so that five years from now (inaudible) late to process. That was a long way of

saying, identify data (inaudible) early in the process.

UNIDENTIFIED FEMALE: I don't know how you want to -- do you want to go around the room or --

MR. ELLENBERGER: All right.

UNIDENTIFIED FEMALE: Maybe we should (inaudible).

MS. BAKER: Just in looking at your points, some of this is stuff I think that we talked about on the call, too. But Rich has kind of put headers there for what worked and areas for improvement. So, I'll follow your format, Rich.

I think one of the things that worked -- and it's along the lines of what you asked us to focus on -- was publishing some kind of a schedule. I mean, it's a little farther upstream because I think we still haven't talked about, you know, what are the priorities and how do I -- we identify the priorities and things like that. But once that's done, once you know what's there, having that out there so all the stakeholders know what's coming when was very helpful. I mean, it was done through SRRD, I'm assuming that you're following that similar kind of format for something here.

One of the areas I think that needs improvement is a little bit of a piggyback on what Bob was saying and that is, you know, as much as can be done up front before we get into the full-blown process, I think, is helpful. Things that can be taken off the table, things that you know need more data or more information, things that you know are going to create some additional work. Having all that stuff done up front was helpful rather than, you know, starting out with a full list of things and going from there.

And then, I think having an identified process that everybody understood, that all stakeholders -- it certainly didn't have to be exactly the same six-step process or wherever we were, but having something where people understood this is how they play a role in this, this is when they're supposed to provide input, this is when they, you know, are supposed to get data back to the agency or whatever. Knowing when their opportunities are to participate in that process, I think, was something that worked very well.

UNIDENTIFIED FEMALE: I would have to agree wholeheartedly with Cindy. I think that the whole

process became so much more positive when people knew what to expect of them. Like the schedule is so very important and important to different groups for different reasons. But the schedule is important. And, also, having a process so that you know -- so that outsiders know when their contribution will be solicited so they can prepare it. They know they'll have an opportunity to speak and to be heard. I think having the process outlined is very positive.

UNIDENTIFIED MALE: I just have some general comments. Several years ago, in fact, I think Warren Stickle and I were working on this, we prevailed upon Marcia to name a public health coordinator. And that was done. Unfortunately, it never seemed to really click. And now -- I just spoke to Jim this morning and I thanked him for taking my suggestion and naming a public health coordinator within SRRD because that's where our issues are. I mean, we're not outside of that division very much. Everything originates right there.

I would like to make a suggestion, though, on this now that we're kind of at a segue here, that to have the public health coordinator available either, vis-a-

vis, at the meetings that we're having up here or at least available by telephone conference so that they can be up-to-date and be on the same sheet of music with the rest of us. I thanked them for getting someone in SRRD and Susan Giddings (phonetic), I think, would be perfectly acceptable for that task.

Also, this is a good opportunity -- and I've said this many times before -- is to get someone here from CDC. And now, we've also got a good opportunity in this regard. We've had a retirement of Dwayne Guber (phonetic), Dr. Guber out at Fort Collins, Colorado as of this past Monday. So, Dr. Lyle Peterson (phonetic) is the new laboratory director there. And there's some possibilities for getting some attendance, perhaps, at these meetings or at least participating on the telephone to get them active and getting them to act as a sounding board for you folks, as well as for us, and that would be helpful.

UNIDENTIFIED MALE: Okay. So, the question, going back to some of the comments a number of you made about the importance of scheduling and process transparency, which are all obviously good things. But

thinking back on -- to the reregistration and tolerance reassessment process. The scheduling that was done that was publicized, the process that was publicized, did it work well, not work well?

UNIDENTIFIED FEMALE: I mean, there's a couple different ways and you guys in the agency probably remember better than I. But when FQPA first passed, there was like these three categories based on, I think, when the tolerances were supposed to be done based on years. That was a good general start for where things are going to go.

But it was through the stuff that we got through TRAC and CARAT that was very specific -- you know, these are the chemicals you expect to have done in this year and, I mean, I know SRRD had a plan, just like a work plan for registration stuff that happens. I think it was when it started getting specific like that that people understood. And, likewise, with the process. I think generally when we laid out the first six steps process or whatever, conceptually it was all fine. But we fine-tuned that as we went along, smart meetings and technical briefings and things that -- along those lines that I

think improved it.

So, I think, you know, when we start with a committee like this, we can conceptually talk about what is it that people want, but once we get into it, you really start to improve that, and we learned a lot of lessons through that.

UNIDENTIFIED FEMALE: In both reregistration and tolerance reassessment, there was -- you know, the focus was very much on the active ingredient and it was supposed to be. I mean, reregistration was set up to look at active ingredients, as was tolerance reassessment. So, the scheduling was based on looking at whatever criteria was for looking at those active ingredients. In the case of reregistration, it was active ingredients registered before 1984. Tolerance reassessment, it was -- you know, there was a priority system.

But I think when you look at registration review, what the statute tells us is that the agency is to look at registrations every 15 years. And what I saw happen in reregistration, to some extent, was there was a lot of focus on the active ingredient, but by the time it

got -- you know, all the issues with the active ingredient were resolved, the actual product reregistrations, all of the unused products, was almost an afterthought.

You know, I'm looking at -- I kind of went back and did some research on, you know, looking at actual -- you know, how many registrations per year were there post-1984, actual registrations that are still active. And it's pretty consistent. There's a 700 or 800 -- those are almost all end-use products and most of them containing previously registered active ingredients. I think the active ingredients that have either gone through reregistration or tolerance reassessment represent the -- you know, the overwhelming majority of active ingredients or active ingredients that have been registered post-1996, post-FQPA.

But a lot of end-use products registered since 1984 or containing active ingredients that weren't going through reregistration really haven't been examined in the past 15 years and I guess what I'm trying to say is maybe we should think about maybe looking outside of the paradigm of scheduling everything by active ingredient

and saying, okay, the statute says look at everything every 15 years, maybe we just start scheduling if a product was registered in -- well, I guess we're already kind of behind. We'll have to look at how to catch up.

But, you know, if a product was registered in 2001, in 2016, that's when it goes through a review. And that will help alleviate some of the issues encountered with products. A lot of products contain multiple active ingredients, and so, scheduling those products has always been an issue. A number of products -- reregistration has been held up because one active ingredient has been reregistered but another one hasn't.

So, I'm just suggesting maybe to this group maybe to think about this in terms of other than scheduling based on active ingredient.

MR. ELLENBERGER: I think Warren was next.

MR. STICKLE: I think going through the tolerance reassessment of the last several years and, certainly, the tolerance reassessment that will be going on through 2006, whereby we're going to be looking at completion of the 9,700 tolerance reviews and reassessments and included in that, probably about 850 or

so food use inerts that are also going through tolerance reassessment.

I think that gives us a very, very good background to look at what has been done, and in reality, I'm not really sure there needs to be any kind of additional similar type work or that level of work to be repeated as part of registration review because otherwise, you'd be absolutely duplicating what you've already just got through doing.

If you go back and look at the legislative history dealing with FQPA and registration review, one of the real purposes of registration review was to take into account the evolving scientific developments and things that would be developing over the next, let's say, 15 years, with the idea, I believe, that the real emphasis ought to be on looking at where the data gaps might be, what potentially might need to be filled. As a result of that, use that as part of the basis for reregistration -- I'm sorry, for registration review. In other words, focus in on the evolving science and the need to fill the gaps.

It shouldn't replace or superimpose itself on

special review. That's -- I'm very happy that Betty is part of the group because special review has its own set of criterias, its own set of triggers, whether it be (inaudible) or groundwater or whatever the issue might be. The whole issue revolving around special review is triggered by certain concerns or issues and I wouldn't want that to be eliminated or gotten rid of. We need to keep and draw a distinction between what is special review and what is registration review so that we don't duplicate or complicate the situation.

UNIDENTIFIED FEMALE: I missed the July 2nd phone call, but -- so I don't know whether or not this was mentioned, but I think it's important to recognize immediately that this registration review -- I do not think that it is anything approaching the equivalence of reregistration or of tolerance reassessment. I think if we start off thinking that that's essentially what we're going to be doing, we're bound to fail. I think failure is absolutely guaranteed.

This is a different kind of process. This process is one where EPA has an opportunity on some kind of a scheduled basis to determine whether or not it needs

to look more closely at certain pesticides. Having said that, I think there are lessons that we can learn from reregistration.

One of the ones that I think is most important is that the process should not even begin to try to be a one size fits all process and the process itself should not tie you in to resource intensive levels of effort for every chemical that comes across the desk. I was talking to Betty and Ted a few minutes ago and this has been something I've, you know, mentioned numerous times. I think one of the first things we need to do is establish criteria at the very beginning for an off-ramp.

As these pesticides come up, you know, there's no reason to look at many of them. There just isn't. There's not going to be yawning data gaps -- and I'll get to that in a minute -- or there shouldn't be, given the fact that we now, at least, have gotten everybody up to this -- you know, the level as far as everybody on the same level. And I don't think that this process should necessarily be used to satisfy data gaps on a per chemical basis because I think then we are back again in trouble.

If there is an -- you know, you can't use this every 15-year review to satisfy each and every issue that the agency has to face. You can't -- I agree with you on that. You can't use it for special review. Special review is something different and apart. It shouldn't -- you should not need to address special review by having to schedule special review chemicals, you know, in this process. You shouldn't need to do that.

When there is identification of a new data need, that should be addressed through data call-ins that go out, you know, more generally to whatever class or category of pesticide you have determined need that particular data. Because among other things, it gives opportunity then to a broad group of people to determine whether or not they can actually form consortia, that they can satisfy it in a more reasonable way than having to test every chemical. Inerts -- I don't think inert ingredients should be part of this program. You already have a system of lists and a group in the registration division that handles this.

I think if there are concerns about an inert ingredient, it moves up to list one, you know, and you

address it that way. I think if you try to solve all of your ongoing kind of stewardship issues, for use of -- perhaps not a perfect term, and try to load it into this, you will fail. I think if you start out as this document here has with this phase one process with an application and identify -- you know, it's 80 chemicals a year, if you just divide by 15 and base it on active ingredients. You can't do what's envisioned in here for phase one for 80 chemicals a year.

I'm not sure that I know what the criteria necessarily are for that off-ramp, but I think those are the kinds of things that we should be brainstorming about here. I think we need to be creative to make this program work and actually contribute to the overall -- the overall --

(End of Tape 1, Side A)

UNIDENTIFIED FEMALE: -- of the whole office to really serve the public. So, that's my speech for the day.

UNIDENTIFIED MALE: I'd like to make a comment before moving on today. That is just to remind us to try to focus on lessons learned in the past as opposed to

what we should be doing in the future. I think we'll get into that later today and in the next meeting. But, again, what worked well, maybe what didn't work quite so well in reregistration and tolerance reassessment.

UNIDENTIFIED MALE: I would like to echo what Sue has said and others, but begin by commending you for giving us a copy of the relevant part of the statute. That's always a pretty good place to start as a grounding. I think that the language is very clear, unlike other parts of FQPA, in speaking to -- about four or five lines down, the goal of these regulations shall be a review of a pesticide's registration every 15 years. That's sort of the capture point.

Not to associate myself with really old people like George or Steve, but I was around for a while, ahead of when Congress did adopt this language and I remember pretty specifically that the debate was mostly around the fact that in 1996 we were, at that point, about seven or eight years into reregistration and we knew and Congress was feeling a certain amount of sense of what was going right and wrong, after having had a couple of misfires prior to the '88 amendments that started reregistration

for real and put resources in place to do that. That while there were a lot of (inaudible) on what we call reregistration at that point in '96, that they essentially just didn't want to have to wake up and in 15 years have a huge backlog of things that hadn't been addressed.

So, they wanted something that was a fairly straightforward framework to maintain periodic review. And there were negotiations that we participated in around the language of what's the right -- the right line number and 15 years was a compromise. The industry wanted something longer and the environment community wanted something shorter. And like a lot of -- hopefully most legislative policy decisions, this is the compromise that democracy brought forward. I think that's really important.

So, this is something that kind of, at least my recollection at least reflects, is a system to make sure that we don't get down the road and have a backlog train wreck like we were facing in 1988 and was beginning to be addressed by 1996 with the reregistration process. But recognition, as the rest of this statutory language

addresses, that there are plenty of other authorities for addressing specific new scientific and regulatory data requirements like endocrine effects, like special effects on infants and children provisions and the FQPA statute and many others. This is sort of the backstop to sweep up everything and make sure that it all fits together.

And it's explicit in saying it ought to be done on a chemical by chemical basis, that's the reference to a pesticide's registration every 15 years. That ought to be the basis for scheduling this and I think that Sue's point that the expectation behind this wasn't that we were going to have another huge backlog, meltdown challenge like tolerance reassessment that was mandated by FQPA or reregistration that was mandated by FIFRA Lite, that this shouldn't be such a big deal.

So, I think that's one of the comments here going back to the slides that you've included in the package today from the PPDC meeting that summarized kind of where we were at. It talks about recapping, that there were only eight comments submitted to the ANPR in 2000. That's now three years ago. And only seven of them from the private sector. The eighth was from USDA.

I think it would be helpful for us if you could give us a little more summary than what was included in the summary slides and followed here at the PPDC meeting because, you know, clearly, this doesn't even begin to reflect the scope of the eight pages of comments that CropLife America, the ACPA, submitted.

So, I think there's a fair amount of additional texture that's already there in the eight comments that came in that might help this group get a firmer grip on what some of the other issues are.

UNIDENTIFIED MALE: Okay, thank you.

UNIDENTIFIED FEMALE: Not to beat this to death -- and maybe I wasn't too specific. But what I thought did not work and what we don't want to repeat in this process is a one-size-fits-all procedure. I think that's absolutely right, that it's very useful to know what the process is, but I think, again, this process has to be flexible. You don't need to review every chemical that comes up on the schedule. You don't need to -- even if you look at the active ingredient, you don't necessarily have to look at the end use products or maybe you want to look at the end use products, but not the active

ingredient.

I mean, I think that there has to be -- that the process has to have a tremendous amount of built-in flexibility and we shouldn't have one size fits all. I think also, too, that the process was reasonably onerous in and of itself and we definitely want to get away from that. Again, that goes to that off-ramp kind of issue and flexibility.

And I think the other thing, and this is, again, echoing what I said earlier and what Jay also said, I think one of the other things that's slowed down the reregistration so much was that activities from various legislative authorities within FIFRA ended up being just piled into reregistration as opposed to maybe addressing some of those issues separately. And so, again, I think that goes back to special review is still special review.

Inert ingredients don't belong in this. First of all, they're not registered. I mean, you can make the argument that they're registered in these products, but again, you have a system for inert ingredients and that's where that should be. So, again, not to be repetitious, but I think those are the kinds of lessons we did learn

and we can profit from in this.

MS. SHACKLEFORD: Let me ask a follow-on question and I'd invite anyone to sort of chime in. But, Sue, you used the word "onerous" and that the existing reregistration program was onerous. I'm trying to understand whether or not you're referring to the fact of the six-phase process was onerous or were there aspects, in particular, of that process that were onerous.

MS. CRESCENZI: Well, I think, for example, the fact that -- and (inaudible) other people -- the fact that there was a RED on -- what was it, (inaudible) egg whites or garlic or whatever --

MS. SHACKLEFORD: Very early on, yes.

MS. CRESCENZI: Yeah, very early on. But the fact if there was any, any effort at all put into that beyond a look at it and saying, oh, well, that one's -- we've reviewed that registration and it's fine and that, again, you've had -- you had to check all of the same boxes for every chemical that's gone through this process. We don't want to be there this time. If we do, it's going to fail. It will 100 percent fail, I guarantee you. I think that is a critical lesson to

learn.

MR. ELLENBERGER: I want to -- before -- I know there are some more comments. I want to recognize a few more people that have just joined us. We earlier went around and identified ourselves. Erik and Carolyn?

MR. OLSON: I'm Erik Olson. I'm with Natural Resources Defense Council. Sorry I'm late.

MS. BRICKEY: I'm Carolyn Brickey. I'm with Protected Harvest and I didn't sneak in this morning. I wish I had.

(Laughter.)

MS. BRICKEY: But I'm glad to be here.

MR. ELLENBERGER: Thank you. Thanks for joining us. Troy, do you have --

MR. SEIDEL: Oh, I -- many of the points that I was going to raise were already mentioned by Sue and Jay. But the only thing I would add, and it's more looking to the future than where we've been, but when we talk about a data need or what is a data gap, I think (inaudible) process (inaudible) what we mean by that, what constitutes a legitimate data need and who decides what (inaudible). (Inaudible) what exactly are we talking

about (inaudible). I think (inaudible) very open process (inaudible).

UNIDENTIFIED MALE: In other words, when we say data need, is it the agency suggesting that the whole new endpoint as opposed to -- not a new endpoint, but for a particular product or an active ingredient. It's an old endpoint, but there's just not -- it's not (inaudible).

MR. SEIDEL: Correct. I mean, we're hearing, just as an example, some registrants have been (inaudible). (Inaudible).

UNIDENTIFIED MALE: Erik and Carolyn, we've been sitting the last half hour sort of talking about lessons learned from the current reregistration process, the process and tolerance reassessment sort of looking forward to the new process. So, please chime in.

MR. OLSON: I guess I would suggest a couple of points. One is that I think there's a need for a clear schedule and criteria developed in order to decide how specific pesticides are put onto that schedule. The concern I have is that it was suggested that -- I think at one point there was a suggestion that EPA was making a Caesar salad instead of a reregistration program back

early in the days, and I think that what is -- reference to the (inaudible) egg issue.

So, you know, I guess the question is really how is the agency going to manage its time and what criteria are going to be used to schedule things. A concern that I certainly would have is that suddenly 12 years into this process, we would realize that we have a reregistration program that needs to go forward and we have three years to do it.

So, you know, I think what's important is to have a very clear schedule for the agency to live by, that it can go to Congress and ask for a budget for, that it can ask for fees for, that it can hold itself accountable for, that it can go to OMB and its (inaudible) process and use to justify its budget request and so on and measure its own performance.

So, I think the need for a clear schedule is important and the -- and some kind of criteria that should be discussed for what goes first and what goes last, so it's not just sort of a random process. That's one point.

And the second point is that I think a lot of

discussions that we've had on what the public participation versus the registrant participation versus grower participation is in that process, we've been concerned that the process isn't always as open as we would like it to be to the public and that we need to figure out a way that we can all agree on for different parties to participate in this process so it's as transparent as possible.

MS. BRICKEY: Jay, I'll be really brief. My number one issue, having been so involved with reregistration back at its creation, is that we develop a (inaudible) in getting to the (inaudible) that we need to be focused on first. And the other issue you know very well, resource management, and I know that that's hugely important to you guys and I certainly don't want to suggest you're not thinking about it. But I think development of a prioritization scheme will possibly help you with the resource management idea and putting together work plans (inaudible).

UNIDENTIFIED MALE: I'm sure you're suggesting that at the beginning of the current reregistration program, the focus on things like eggs and garlic and

clove oil and stuff wasn't the --

MS. BRICKEY: No, it was really bad, and that was because we didn't develop a prioritization scheme either in the legislation or initially in the agency process and I just think that's critical.

UNIDENTIFIED FEMALE: Right. And, again, there was -- everything was subject to the same kind of -- you know, this is the box we've built and everything has to go through this box and every check -- every square in the box needs to be checked and we don't (inaudible).

UNIDENTIFIED MALE: You know, if we're looking at 1,200 or so active ingredients and you're looking to try to do that in the 15-year period, you get back to the numbers that Sue and others were talking about and that's doing 80 a year, and there has to be some level of priorities on what to do. If you treat them all equally, you're going to take about 90 years to get this process done. So, there needs to be some kind of a focus on what really needs to be looked at, where a data gap exists and what are some of the things that have or fit a criteria for an easy off-ramp so you don't spend an equal amount of time on something you've just reviewed three years

ago. So, there needs to be some kind of a conceptualization as to what the scope and what the priorities are so that you actually can accomplish what you set out to do within those guidelines, that you want to try to do 80 products a year or 80 active ingredients per year. Otherwise, you'll not get done. You'll get 12 years down the road and realize you've got 800 active ingredients to do and no way to get it done.

UNIDENTIFIED MALE: It really is a daunting task for the agency. The 15-year cycle, not only is it to look at the active ingredients (inaudible), but if you look at the numbers of end-use product registrations, if my math is right, that's also about 1,300 end-use product registrations to look at every year, too, for a 15-year cycle. So, either way you cut it, the numbers are huge.

UNIDENTIFIED FEMALE: Which is, again, why we have to think outside the box. I mean, there have to be criteria for establishing what the level of review should be up to and including absolutely none. Looked at it, it's fine, it goes off. Remember, you have existing authorities if something comes up at some point, and where there is a critical problem, you expect

(inaudible). This process should not carry all the water for the agency, you know. You have, as Jay said, other authorities and you don't want to load this process up.

UNIDENTIFIED MALE: (Inaudible) and I don't think (inaudible). (Inaudible) issues of scheduling and (inaudible) scope of the review will be and maybe no review (inaudible) and then some element of (inaudible) built around that. But then the obvious (inaudible) given the nature of public (inaudible) because people are going to say in 2007 (inaudible). (Inaudible) and here we are seven years into it and 802 have been concluded, and even though (inaudible). Do you have any (inaudible)? Again (inaudible). (Inaudible) process.

UNIDENTIFIED MALE: Okay. (Inaudible).

UNIDENTIFIED FEMALE: I agree with a lot of the comments that have been made as far as, you know, for new data requirements that that should be done through a DCI or the mechanism. I think, again, we have to -- this is not everything has to be looked at within 15 years. I'm looking at, everything is looked at every 15 years, and so, if we're looking at active ingredients, I think the agency registers, what, 10 to 12 new active ingredients a

year. So, I would see that the workload would be 10 to 12 active ingredients every year once -- you know, we've got the gap between 1984 to the present that we have to deal with. But, again, a lot of those are being dealt with through tolerance reassessment.

But in a 15-year period for scope of products containing an active ingredient, the agency's policies tend to change over time and even for a product registered in 1995 with a certain active ingredient versus a new product registered containing the same active ingredient 15 years later, there could be very different -- you know, a lot of differences. I see this process as a way of let's always make sure we bring everything up to -- and whether it be an active ingredient and it's -- as I said, it's 10 to 12 a year. Let's make sure for that active ingredient, 15 years after it's been registered everything's in place.

But for, you know, other products, I hear a lot from registrants, being in -- working with other registrants, I hear from end users like Bob's group. One of their big complaints is always inconsistencies in labeling and that, you know, this product has certain

restrictions and registrants complain because -- well, I have to have these restrictions but this other product doesn't. And this -- you know, maybe this is a mechanism for taking care of those kind of issues and also looking at active ingredients, but not that we have to look at all active ingredients every 15 years, only those that were registered 15 years ago.

UNIDENTIFIED MALE: (Inaudible) clarification. I think this is what I'm hearing, but I wondered if (inaudible). I don't think anyone's suggesting that (inaudible) look at reregistration should be taken off the table necessarily to (inaudible) don't really have (inaudible) a lot of resources. So, I think (inaudible) not saying don't consider (inaudible) unless there's some scientific or solid reason for that. Is that (inaudible)?

UNIDENTIFIED FEMALE: Well, yeah, or don't look at end-use products or don't even look at the chemical if there's nothing -- you know, yeah. I mean, it's -- building and flexibility, I think, is what we're all suggesting.

UNIDENTIFIED MALE: I guess what I would say is

I don't think it's legal for the agency just not to look at a chemical, obviously. But what probably is appropriate is if after a preliminary screen of looking at what data are available and after soliciting some kind of comment on it, if there doesn't seem to be any concern, well, maybe you do need an off-ramp that would simplify the review because if you don't have that, I don't think you're going to get to the high-risk chemicals that you really need to worry about.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: So, you know, I think -- you know, there needs to be some kind of process. So -- in case something has come up that the agency isn't aware of or whatever, that there's a routinezed process for considering that. I don't think the agency can just sort of have somebody sitting in a room without talking to anybody and just saying, well, this one looks fine, this one looks fine, this one looks fine.

UNIDENTIFIED FEMALE: Right. No, I had mentioned before we need to establish criteria.

UNIDENTIFIED MALE: Right. You need criteria and I think you need some kind of process, you know, and

it might not be one Federal Registry notice for each individual end-use product. But it might be, you know, a -- based on criteria, the agency determining, after reviewing all the evidence that's available to it, that it looks like this one doesn't deserve a lot of attention and I'm proposing that it's going to set that issue aside and consider it reviewed unless some new evidence is presented to it.

But I do think it's critical not just to have sort of inside the agency, inside the Beltway kind of a view.

UNIDENTIFIED MALE: Patti?

MS. BRIGHT: I think, Jay, everyone here has acknowledged that, obviously, there's a tremendous amount of work to be done and, you know, I think as Cindy said, it's really important that we get a process going, that all the stakeholders know what's happening, when it's happening.

My experience, I haven't been here as long as some of the others, unfortunately, but my experience has really come from the reregistration side of things and while I think it's important to get a schedule, to get

the priorities, to develop all of those things to make sure that we know we're moving along, from the reregistration side of it, I think the important lesson to be learned there is that there are a lot of speed bumps that can happen that can really dumb up the process once it starts, and we've seen the reregistration, that some of these things can be in reregistration for two years, longer, benthion.

And, you know, part of the problem, I think, that we've run into there again and again is we run into the process where stakeholders are getting -- some stakeholders are getting involved at the end. So, we end up having all these speed bumps, whether it be lawsuits or contentious arguments over data or whatever, whatever. I think it's important that we do get the stakeholders involved from early on. Maybe I'm kind of jumping the gun, but I think it's an important issue.

If you want the process to run smoothly, as Cindy said, you let the stakeholders know early on and that's all the stakeholders. You know, reaching out to the non-agricultural and non (inaudible) as well. I think it's important that you have all sides represented.

I think George made a very good suggestion in terms of having CDC representatives here. I think that they were -- it was very useful at the last PPDC meeting to have Gary Clark and Jane Googler here. USDA is often -- is always involved. I think these things are needed. I think you also, again, in terms of smoothing out the speed bumps, we need to have a Fish and Wildlife Service representative at these meetings as well, and that's something that I've not seen happen. But, again, you know, that can smooth out the speed bumps a great deal.

Sue suggested developing that off-ramp. I think that's a very wise thing to do. I would strongly agree with that. Again, I think you need to look at all the stakeholders and look at also the ecological concerns and have some guidelines there for developing those off-ramps. And then as Erik said, you know, I would agree with Erik that this needs to be a very open process and the more open we make it from the beginning, the less problems you'll have later on. So, I guess that's where my focus leads you.

UNIDENTIFIED MALE: Thanks. Dan?

MR. BOTTS: Going back to Jay's look at the law

and the language that's there, just a couple of quick questions. I missed the conference call so you probably covered this on there. I guess from an agency's perspective, what do you envision the end product of this registration reviewing being? Is it a TRED, is it a RED, is it an analysis of a RED that says it has gone through reregistration and these conditions were put on the ability to continue registering all the products that have that active ingredient now meet that? What do you envision the end product of this process being? Is that a fair question?

UNIDENTIFIED MALE: Yes, that's a great question. Optimally work issues -- what do you want it to look like, but then how do you get there?

UNIDENTIFIED FEMALE: Frankly, I think that's one of the things that this group could actually make recommendations on, what should the end product of a reregistration action look like?

MR. BOTTS: The reason I ask it is because, I mean, I see a different condition for something that has gone through reregistration versus something that was registered since 1996 that would be a product that was

registered under the new law that hadn't gone through reregistration. Then you've got a whole universe of other things that were out there that are kind of caught in never-never land.

And one of our big issues at the end user side of this thing is you get a RED published and there's conditions in there and then, all of a sudden, you start seeing active ingredients with differential labels that start showing up out in the field where you appeared -- think that there would be much more consistency between labeling based on what the REDs said people were supposed to do at the end of the day. I guess that's part of the question I've got is, how do you -- what's the end product?

UNIDENTIFIED FEMALE: Well, I actually -- I can't resist these visionary questions.

(Laughter.)

UNIDENTIFIED FEMALE: I can resist a lot of other stuff, but the visionary ones are always stimulating. I actually spent -- when I came to the agency a long time ago, we were in the midst of the first effort to do reregistration and it started off with the

assumption that most of the data that we had was good and didn't need to be looked at again and, therefore, we could just build on that, which is part of what I think I'm hearing.

In that particular case, it proved to be a bad assumption. It was probably a good assumption in that we had no additional resources to do the work of reregistration. So, if you don't have any more resources, then you need to keep your registration program going. Our starting place, I think, had some common sense to it, but it didn't prove to be viable because the studies didn't prove to be, I guess, quite what everybody thought that they might have been. I'm not suggesting that that's actually going to happen to us again in the future because I think we've done a lot more to shore up the databases and to document the quality of the databases and to maintain the sort of records that were not maintained prior to EPA starting the first effort of reregistration.

But then I've lived through several other reregistration programs, including, I guess, FIFRA-ADA, had some involvement in that. I had the feeling -- and

it may just be a personal feeling, but I thought it was a feeling shared by lots of different folks that were like, wow, this is too big to have to update all at once. We actually never want to do it again.

So, what is it that we can do that actually creates incentives for what I would call keeping things up-to-date as you go along, but making sure that that's actually what you're doing? Because when you've got a program with as much variety and multiplicity of both chemical product and uses, it can be very hard to make sure that you're being sort of systematically updating things as you go and there are all kinds of, I think, distractions and disincentives both on the agency side and the registrant side to not always be perfect up-to-date.

But anyway, my personal vision, Dan, is that I'd like to create a process for registration review that encourages, as much as possible, this sort of continuous updating so that when you go to the official place to declare completion of the registration review, whether it's for the chemical or the products associated with it, it is relatively simple because a lot of the work has

already been done during that preceding time period.

I don't actually have a picture of the document that we would produce. I'm pretty sure we need a document. For all the accountability reasons, you need a record. It seems to me the documents could be highly variable, depending on if you really have a lot of new data that really needed to be reviewed. I'm presuming we would still want to sort of document the results of our review in the ways that we're doing now or with improvements that you might help us identify.

On the other hand, if what we decided was we had lots of labels that needed fixing, maybe that's actually what our record should be, is sort of what were the fixes and the basis and rationale and time frames for doing that. And I certainly don't know what the acronym is, but we've got REDs, IREDs and TREDs, so it's probably got to rhyme, I'd think. So, you can figure out, of course, what the name of it should be.

UNIDENTIFIED FEMALE: Oh, we need to start with a new name.

(Laughter.)

UNIDENTIFIED FEMALE: All right, if you don't

like it. But somehow, you know, you need a pedigree. So, that's kind of -- so, it's more like I have this idea about what the process should be like. I actually think the process, in a way, and the kind of attitude that it generates in everybody -- because it is always easier to keep up-to-date as you go along. I'm thinking about my office now and I need to go back and look at it and all the piles I have to go through for some reasons, and it's like, oh, I wish I had kept this up-to-date as I went along. So, I don't know if that helps any.

MR. BOTTS: Can I just follow up just real quick?

UNIDENTIFIED MALE: Yeah.

MR. BOTTS: Just one question. And I don't disagree with what you said, Anne, but I guess one of the issues I've got is, all the other criteria and their limitations on other processes. I mean, you've got special review, you've got other things that are there. What level of trigger would require a -- I mean, you've got specific triggers for special review, you've got specific triggers for other things to say, this is when you have to do it. So, you've got a new issue that pops

up legislatively or something down the road. Does that automatically trigger a need for reregistration review?

If you had another endocrine disruption type issue that comes along that's legislatively mandated to the program and you have to now look at this, does that start the talk over again or does that enter into this or do you have to put that in the place in the process? I mean, I just -- how do you determine -- I guess it gets to the scope. How do you determine the scope of what's actually included in the review -- in this process?

I don't envision if we get to the end of reregistration with the type of review that's there, there's going to be a tremendous amount of data gaps. There might be additional information needs to focus on some issues that are outside of any registration guidelines or anything else that needs to be done to get information to answer specific -- probably site specific, crop specific type questions on the potential risk identified in a registration review. But I don't -- I guess -- I'm having a hard time getting my arms around how to frame the criteria or the process. And I agree with Sue, it's different for kitchen waxes or -- that

have a pesticide in them versus anti-bacterial soap versus agricultural pesticides versus things that go into a professional home PCO type deal. There's going to be different things that trigger needs for issues around those when you get to the specific registration issues beyond just a general chemical safety or individual (inaudible).

UNIDENTIFIED MALE: Dan, wouldn't a starting place be if the agency would finalize the update of Part 158 in Code of Federal Regulations? I mean, that held in terms of one centerpiece -- if you look back at all the progress that's been made, that, to me, is, you know, one big piece that's still dangling right now over the last 20 years. So, that might be kind of a leading suggestion of something that would guide this registration renewal process.

UNIDENTIFIED FEMALE: That would also fit with your concept (inaudible) continued improvement. So, I think -- I like that. I think it makes sense. (Inaudible).

UNIDENTIFIED FEMALE: But I think that we have to remember here the discontinuous updating if you're

thinking about animal studies or guideline exposure studies. You know, there's that whole issue of compensability and whether or not it's required and all of that. Those are just nuts and bolts, but they're nuts and bolts that are important.

But also, too, I think that there has always been -- and this is a personal view. I think that there is useful information that the agency could take a look at that isn't necessarily a pesticide assessment guideline study that you should be encouraging people to provide and without -- you know, not to say that you should be accepting junk, because that's not what I'm suggesting. But there are epidemiological studies, perhaps, or there are other, you know, perfectly valid kinds of information that you could be looking at here.

I mean, I just don't -- I guess I have a problem about this expectation that people would be continually conducting animal studies and updating files. That's -- I hope we're not talking about something like that. But certainly when it comes to the exposure side of it, which I think there needs to be a lot of refinement, that there should be, you know, some flexibility there and working

on mechanisms to protect very expensive data because if you don't, you're not going to get it. That's just something else we need to brainstorm about.

UNIDENTIFIED MALE: Steve, and then we're ready for a mid-morning break. I know I am.

(Laughter.)

MR. KELLNER: Well, I'll hurry up then. I'm going to go back, I guess, to what we've learned, to your question, Jay. And the procedures that we have thus far with tolerance reassessment and the publicity of what those procedures are, I think there's not -- I think there's a huge improvement that can be made there. Those of you who are dealing with this every day, of course, you know this stuff cold, I'm sure. But for a downstream user, a registrant who wants to become involved here, there's not any one place where everything is laid out. I know you've got the six provisions and that type of thing. You've got a proposed regulation that was never finalized and that was several years ago.

There needs to be something, some policy, something that I can go and people can go look for and get up to speed with how this thing really works.

I think we have to have consideration of the registrations themselves and what a registration brings. There are requirements, there are -- you know, it's not just a piece of paper that you have that can be taken away. And there's a -- I think, a unique opportunity for those folks to participate and we need to get them involved and we're starting to do that with permethrin, the latest area that we're starting to deal with.

But CSPA wrote a position paper, which we ran by Steve Johnson -- I'll be happy to give you a copy of that -- a year ago, July 18th a year ago, saying that there was no bias built in here, that we're going to lose these chemicals unless there is some fixing of this and getting us involved early.

The smart meetings themselves -- you know, I've asked people -- I know there's no real name or acronym, I don't think, for a smart meeting. Nobody knows.

UNIDENTIFIED FEMALE: As opposed to a dumb meeting.

MR. KELLNER: Right, right.

(Laughter.)

MR. KELLNER: So, you hear, evidently they've

had a smart meeting, they've decided what uses they're going to have. What the hell is a smart meeting? Well, I don't really know, nobody really knows.

We have to be careful and clarify, I think, and make -- and set these procedures out to people. That's the first step. We're going to catch the trolley. You know, that's the first step to do that. And I think we've been lacking that.

We need product (inaudible) to participate in the non-ag segment in particular, but everybody. And I think what Dan is saying here is, what is registration review? What is it? That's what we have to determine. I think this is a very good effort that we should begin.

And, finally, I do think that -- in conjunction with what Sue said, we're not here to start the whole program all over again. The agency has authority. We need to pick out what was really meant by that provision and deal with it. So, I think those are sort of learning experiences, in my opinion.

UNIDENTIFIED FEMALE: (Inaudible).

(Laughter.)

UNIDENTIFIED MALE: (Inaudible) had his card up.

UNIDENTIFIED FEMALE: No, I had mine up first.

(Laughter.)

UNIDENTIFIED MALE: Do you want to take a break now or do you --

UNIDENTIFIED FEMALE: I'd like to make my comment because I might forget it and then (inaudible).

UNIDENTIFIED MALE: All right.

(Laughter.)

UNIDENTIFIED FEMALE: Sort of the way I'm thinking about this is you develop a definition or a template for what reregistration is and then every chemical has to measure itself by that or the company has to measure it by that template and then develop a tiering system, you know, a tiering system, one, two, three, whatever, that has criteria for each tier and use the tiering system to publish a list of chemicals that fit in a particular tier and (inaudible) prioritization (inaudible). That's all (inaudible).

I like the continuous improvement idea and I like -- I would like us to think about the incentives that we could build into that that would make it advantageous to continuous improvement.

UNIDENTIFIED FEMALE: (Inaudible) clarify that. I didn't mean to suggest that I had (inaudible) year after year (inaudible) generating more studies.

UNIDENTIFIED FEMALE: Okay.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: Okay.

UNIDENTIFIED FEMALE: But keeping up-to-date is really different than always generating (inaudible) studies.

UNIDENTIFIED FEMALE: And I think that's where we need to -- because the agency has focused so much in the past on pesticide assessment guideline data -- and I think there are other things that we could be looking at, too, that are very helpful in terms of making some (inaudible).

UNIDENTIFIED MALE: I'm not going to stand in front of the bathroom door, so I'll comment later.

(Laughter.)

UNIDENTIFIED MALE: Why don't we take a break and get back at five of 11:00.

(Brief recess.)

MR. ELLENBERGER: Ray, why don't you go ahead?

MR. McALLISTER: Should we start?

MR. ELLENBERGER: Yeah.

MR. McALLISTER: Yeah, I wanted to just raise a couple of issues. One is that I think the process -- I would agree with what Carolyn had suggested about the need for some clear criteria for tiering and priority setting, which is consistent with what I had suggested earlier. But I think it would be worth this work group spending some time to try to develop some such criteria with EPA and to figure out a way to tier it and to set priorities for what's going to be reviewed and I want to reiterate the importance, once that process is done, of having some kind of schedule so that EPA can go up to the Hill, to the Appropriations Committee, and say this is how many we've got to review, we need the funding to do that, et cetera.

The other two points I wanted to raise are the -- there is a lot of data that's routinely coming in to EPA and -- for example -- and there are going to be new tests developed. The endocrine stuff, we haven't really figured out what's going to happen with it. But I think there needs to be a clear process for feeding new

information into the reregistration process, and I'm not sure that a lot of thought has been given, at least I haven't given a lot of thought, to how you make sure that you don't just shut down the whole process on the one hand, but that you do consider and build in consideration of the new test results. So, that might mean that you set as a higher priority those chemicals where you might have some of the new data that is called for.

I guess I also wanted to agree with what Patti had said about the need for all the federal agencies that have specific statutory authority and responsibility to be involved in this process to be built into the process from the beginning. So, USDA absolutely, of course, but the Fish and Wildlife Service, I think, has never really been a full participant in the process and needs to be built in to the process as a matter of course, in these meetings, as well as, I think, the reregistration review process.

And finally, I think one way -- I had mentioned earlier the need for a clear public participation process. I think there's a lot -- there are technologies now available that the agency hasn't always taken

advantage of that might also help. The agency's website, for all of its benefits -- I would agree, actually with what Steve had said about how we need sort of a clear central source of information. We use EPA's dockets frequently, and to be honest, they are often not up-to-date, they are incomplete, they are -- you basically can't get the information that you need from them and you have to submit a Freedom of Information Act Request often.

I wonder if there isn't a way to set it up so that EPA routinely creates electronic files when they receive these documents through PDF files, you can now just throw things into a Xerox machine and they create PDF files, that could be posted on the website.

UNIDENTIFIED MALE: We've just done that.

MR. McALLISTER: So, I think that there are -- if your IT people are involved in the beginning, you know, you could have a much more open process without as much paperwork having to go back and forth, with fewer resources dedicated to it, and folks like us and people all over the country could have much more ready access to the key EPA documents. Because very often we find it's

the registrants and EPA are the only ones that have the key documents and we're way behind the eight-ball if we're trying to catch up.

So, I think building in a concept of making sure that the documents are readily accessible, if that's built in to when you receive the document, you just throw it on the machine, you're going to be making copies anyway, why not create a PDF file while you're doing it and have that thing available broadly?

UNIDENTIFIED MALE: For those of you who maybe are not -- or don't know this yet, we -- EPA, or at least the Pesticide Program, now does have an electronic docket system. So, it's -- I think that's really improved the efficiency and access as well.

MR. McALLISTER: Right. I guess my comment -- which is a start. But a lot of the documents don't go into the docket and often all that's available is, at best, an index. So, you know, I certainly commend you for starting down that road because a lot of other offices at the agency have not started down that road yet. So, I think it's a great start.

UNIDENTIFIED MALE: Okay. Carolyn?

MS. BRICKEY: Before Betty went out the door she asked me to say more about what I meant about change.

UNIDENTIFIED MALE: Okay.

MS. BRICKEY: And, you know, I was talking to Warren at the end and he had two or three good ideas for what ought to be the first group of chemicals to look at, you know, looking at the ones that have (inaudible) that didn't have a tolerance reassessment and vice versa. (Inaudible) that didn't, you know, participate in those processes, both of (inaudible) good criteria.

The juggernaut for me is, how do you reconcile the first tier, which just say for the sake of discussion is the easy tier, with the last tier in terms of priority to getting them done? I know there's a lot of feeling that you don't want to wait until you're 14 to say, all the chemicals in this tier are reregistered with the exception of (inaudible) or something versus a group of chemicals that you're going to want to look at as soon as possible to try to deal with (inaudible) issues that (inaudible).

So, there's a conflict there inherently. So, that's going to be something tough to work through and

think about how to do it.

But I think as far as the tiering itself goes, I think we can pretty easily come up with some decent criteria and I think they can be refined over the next (inaudible) talk more about it and -- you know, I don't -- maybe I'm being a Pollyanna this morning since I've had this cup of coffee, but I don't think that's going to be a big conflict for this group or a group of PPDC. I think the more difficult thing is how do you reconcile the easy group with the hard group in terms of tiering. I don't think anybody wants us to be stuck at year 12 and decide we've got to do hundreds of chemicals like Dan mentioned. That's just not workable.

So, if you're going to do 80 a year, what 80 are you doing and how would you deal with that (inaudible)?

UNIDENTIFIED FEMALE: So, what you're saying is we start out with the universe of all the active ingredients currently registered and say that whole universe has -- everything in it has to be reviewed in the next 15 years?

MS. BRICKEY: Right. (Inaudible) post-84 chemicals is what we're talking about in this first

calculus, right?

UNIDENTIFIED FEMALE: Well, that's what I'm trying to --

MS. BRICKEY: Right.

UNIDENTIFIED FEMALE: Okay. So, you're saying post-'84?

MS. BRICKEY: Yeah, right.

UNIDENTIFIED FEMALE: Oh.

UNIDENTIFIED MALE: I think with the tiered system, and I've talked to Warren quite extensively about it, tier one would be your 84 to 90 where there's no tolerance, no RED, those should go to the top of the list. Tier two would be a present tolerance reassessment but no RED and then tier three would be compounds that have gone through the RED.

UNIDENTIFIED FEMALE: Not necessarily.

UNIDENTIFIED MALE: Well, just -- I'm getting heads shaking over there, though.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: I wasn't thinking of it the way you just articulated. I was thinking the first group that you want to really look at after you've got

your template for what reregistration of a product is, I was thinking that you'd probably want to put all those in that group initially before you start doing the tiering process.

UNIDENTIFIED FEMALE: I guess I'm getting a little confused about what are we -- SRD through reregistration and FQPA reregistration, we're going to have some overlap, aren't we, if we start doing this? I mean, aren't some of those things that you're concerned about getting done first also high priorities in the reregistration process?

UNIDENTIFIED MALE: And it goes straight back to this easy off-ramp.

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED MALE: I mean, to me, it's become very clear that identifying early on what products can be moved off the list is going to be crucial for --

UNIDENTIFIED FEMALE: You're not moving them off the list. You're saying that they are either, in fact, reregistered --

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: -- based on the

definition.

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: Or that there's some very simple things that need to be done to complete a reregistration. That, to me, is what the easy tier is.

UNIDENTIFIED FEMALE: Um-hum.

UNIDENTIFIED MALE: Wouldn't you normally say -- I mean, I think we'd want to say the program starts (inaudible) and would start (inaudible) gets looked at 15 years after (inaudible) in the order in which it last (inaudible) registration or reregistration decision.

UNIDENTIFIED FEMALE: Well, you could do that if (inaudible) having continuous reregistration (inaudible) chemicals that are (inaudible).

UNIDENTIFIED MALE: But it is (inaudible) so they (inaudible) haven't had (inaudible).

UNIDENTIFIED FEMALE: See, I think -- but they have. There's a lot of chemicals that were registered after 1984 that have gone -- undergone reassessment or assessment under FQPA either because they've added uses and, therefore, they had to be evaluated under FQPA in order to -- I'd say a good number fall into that category

and some of them have undergone reassessment.

UNIDENTIFIED FEMALE: Then they may fall -- they may fall out of the first (inaudible) and just be part of the (inaudible) group. But you still have to look at it to make that determination.

MR. ELLENBERGER: Can I -- I want to put on my facilitator hat here and just sort of break in. It sounds to me like we're starting to work issue number two which is next month or something like that.

UNIDENTIFIED FEMALE: Right.

MR. ELLENBERGER: And, you know, it's interesting stuff and I hate to disrupt good conversation and discussion and debate about something, but I want to stay -- try to get back on the agenda and hopefully -- Ray's got his tag up and I hope he's going to talk about lessons learned.

(Laughter.)

UNIDENTIFIED FEMALE: You know, Jay, what I think the problem is, is I really see what we've moved into as scope more than issue two.

MR. ELLENBERGER: Yeah (inaudible) that.

UNIDENTIFIED FEMALE: And I think that people

are having a hard time talking about just issues learned without talking in context of what is the scope of what we're talking about.

UNIDENTIFIED FEMALE: Right, exactly.

UNIDENTIFIED FEMALE: I mean, that's where I think people are trying to go.

UNIDENTIFIED FEMALE: And I think we've beat lessons learned pretty much -- as much as we need to.

MR. ELLENBERGER: Well, I was going to ask, are we sort of done with --

UNIDENTIFIED MALE: Yes.

UNIDENTIFIED FEMALE: Yeah.

MR. ELLENBERGER: Okay.

UNIDENTIFIED MALE: I'll agree with that.

UNIDENTIFIED FEMALE: They're precocious.

MR. ELLENBERGER: All right.

UNIDENTIFIED MALE: I think the scope is really an important issue because --

UNIDENTIFIED MALE: I think the process for calling on people is breaking down.

UNIDENTIFIED MALE: I'm sorry.

UNIDENTIFIED FEMALE: He wants tents.

UNIDENTIFIED MALE: Oh, you want --

UNIDENTIFIED MALE: I mean, we had a conversation going on here without a process for calling on people to talk.

UNIDENTIFIED MALE: Okay. You did have your tent up, your card up, so --

UNIDENTIFIED MALE: We learned some valuable lessons from the early stages of reregistration, which sort of broke down in later stages. In the early stages, we had a very clear process for identifying what data were required on those compounds to undergo reregistration. The registrant filled out a rather lengthy series of forms identifying the data that were available and the data that were needed in making a commitment to (inaudible) that data.

Because we've been through that once or will have been through that once, I don't see the process for reregistration review needing to be quite as complex, though we should have that type of process for identifying how well a given chemical, when its date comes due after 15 years, meets the then current data requirements and deciding whether there is an obligation

to produce anything else. So, that process -- clearly defined process of identifying data requirements, how well they're met and what (inaudible) you needed is something we need to follow from registration in reregistration.

UNIDENTIFIED MALE: I think what you're saying, if I understand it right, it gets back to what Jay was saying earlier about 158 --

UNIDENTIFIED MALE: Yes.

UNIDENTIFIED MALE: -- as sort of a bright line or the --

UNIDENTIFIED MALE: Yeah. At that time, in 1988, 1989, we had the comprehensive list of the data requirements. The agency developed acceptance criteria for the various studies so that if a registrant did that initial evaluation, it is subject to review by the agency and then the data (inaudible) are issued.

UNIDENTIFIED MALE: Are you saying that the earliest data -- I think I was around and involved in that -- was phase -- phases two and three, I believe, FIFRA ADA?

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED MALE: But that very systematic process is a good -- was good?

UNIDENTIFIED MALE: Yeah. And where it broke down is we had an agreement very early on that as of this date, that's what you need to satisfy reregistration and it broke down because any subsequent change in data requirements or additions then was rolled into reregistration guaranteed, but reregistration would never get done as it was originally envisioned because you keep adding things to it and that has to be done before you can get your RED so you're never done.

UNIDENTIFIED MALE: Margie just slipped me a note that as we talk, try to use the mics or it won't get picked up.

Okay, so we started off with a very systematic process of sort of what are the rules, if you will, for a data -- for a chemical's database and then as new issues came up, as science moved on, as science policy changed, those rules started -- for a given active ingredient anyway, started breaking down and you started, I think, getting into problems that some of you were saying before the break about these new issues being thrown into a

chemical that then slows down the process, stalls it, if you will, rather than keeping on this high -- high quick production streamline system.

UNIDENTIFIED FEMALE: Let me ask a follow-on there, just as a point of clarity for my benefit. For many of the chemicals, science policies -- well, science policies evolve, not necessarily for many of the chemicals, they simply do. Oftentimes, data are submitted and they may not necessarily satisfy data requirements, so we might end up with multiple studies that, on aggregate, satisfy a data requirement.

You might end up with a situation where as you're working through the reregistration of a compound, additional data might help refine a risk assessment so those studies might not necessarily be called in but could, in fact, be voluntarily submitted.

And what happens with the reregistration process is the reregistration process is driven by how timely those data are received and viewed, et cetera. Are you suggesting that as a part of each process we contemplate or the agency contemplates putting a stake in the ground and the data and science policy that are in place exist

as of that date?

UNIDENTIFIED MALE: Well, for purposes of accomplishing either reregistration or tolerance reassessment or a subsequent registration review for achieving that specific need, yes, you need to drive a stake in the ground and say, you meet the requirements in effect on this date and it may take you two years to meet them, then you have met that registration review requirement. You don't come back in two years down the road and say, well, in the interim, this new study has come in. You require that new study under your separate additional other authority, not under the registration review. So, you can, in fact, say that for that compound, because you have met those requirements, in effect, on that date, registration review is complete.

UNIDENTIFIED MALE: I'm very sympathetic to the need to have sort of a fixed set of expectations for the registrant so that the registrant knows what's expected. I think that part of the issue, though, is that, frankly, the special review process, which would be the alternative method, is kind of broken, at least in our perspective, that it takes so long. So, if we're going

to rely upon other proceedings to deal with what happens in that situation, we need to have other proceedings at work.

So, I guess what I would think is that, you know, consistent with what you were saying about how we need to sort of have some flexibility in the process, if you've got suddenly a new study that comes out that suggests there's a problem with a chemical and, you know, we are a month away from EPA making a decision on that chemical, there needs to be some process to make sure that that study is considered and that it bears the need for subsequent studies that that's dealt with. You know, there is a tension between that and timeliness of the process, which often is how EPA gets caught in the bind its in.

But unless there -- and frankly, often those new studies come in right under the wire, right at the last minute for a variety of reasons. So, you know, I think there is a need for a clear expectation of when the decisions will be made, but there needs to be some degree of flexibility where if a very significant piece of information comes in late in the process, that that

doesn't derail the process, but that it, at least, is considered.

So, you know, I think it would be useful to have a clear sort of set of principles for how EPA is going to deal with that recurring problem, because it seems like a piecemeal response now and it would be useful to sort of think through what happens when important studies come in at the last minute. Because we've seen this for tolerance reassessments and we've seen it for REDS repeatedly. I'm not sure there's a clear consistent process from chemical to chemical.

UNIDENTIFIED MALE: Let me suggest -- I think as we already have started to do -- moving into the discussion about scope of registration review and spend some time questioning that out a little bit more before lunch. I know there's been discussion already this morning and our first teleconference call about what should it include.

I mean, we've heard everything from put more focus on end-use products, change the balance between end-use products and the technical active ingredient, what about inert ingredients, is that a separate process,

separate program, but knowing that if we put more focus into end-use products, all end-use products have inert ingredients, so there is, obviously, some built-in, sort of inherent focus on inert ingredients as a part of that. What about tolerances that have been reassessed? Those 24Cs, those experimental use permits. So, there's a number of regulatory -- very distinct regulatory pieces that could be considered in this whole definition of registration review.

So, thoughts -- more thoughts or comments on that.

UNIDENTIFIED MALE: Is there a checklist (inaudible) developed?

UNIDENTIFIED MALE: Sure. You mean as technical as end-use products?

UNIDENTIFIED MALE: Well, no, no, no, no, what the things are that have to be reviewed in the registration review.

UNIDENTIFIED FEMALE: That's why we're here.

(Laughter.)

UNIDENTIFIED FEMALE: I think from a practical standpoint, you're going to have to make your -- you're

going to have to organize this on an active ingredient basis. I just -- I just don't see how trying to organize it on a --

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: Yeah. And then I think it really becomes an issue of are there any issues to be considered with the active ingredient? If there are, consider them. If there aren't, you know, you've taken a look and you've made a determination that the database is where you need it to be. There's no additional data. There are no 602 reports, whatever, and you take a look at the end-use product labels because you really shouldn't need data for those end-use products because, you know, essentially they've either been reregistered and submitted new -- acute data packages were necessary or there would be registration.

At that point, I think the biggest issue would be whether or not the labels are in order. If they're in order, then, you know -- I mean, again, I don't know that that's the end-all, the be-all, but those are -- you know, you have to kind of consider in a stepwise, do we have issues with the AI? Yes, no. You know, do we have

issues with the end-use products? You know, yes, no.

Again, I would submit that inert ingredients as individual chemicals not part of a formulation do not belong in this process. Among other things, they're not registered. And you do have an existing process. Again, I would say that you just can't load everything into this process.

UNIDENTIFIED MALE: Other thoughts or comments? I'm sorry, who's next?

UNIDENTIFIED FEMALE: First, relative to scope, I think given this is under FIFRA Section 3 and they're talking about registrations, I would expect that really what the scope of this is is to look at registration -- a Section 3 registration, registration granted under FIFRA Section 3, that that's what is subject to review. I don't think it would -- you know, I think there's -- under -- an EUP is not a registration. It is a permit to collect data. A 24C is a registration of sorts, but it's not a Section 3 registration. So, I think just in the matter of scope, that the registration review should be Section 3 registrations.

And, again, you know, I think, looking at how it

might be organized and having looked at what -- kind of a summary of new registration -- kind of on a summary basis, if you look at the number of new registrations still active granted between 1984 and 1990. We quickly see that there's about 800, 900 registrations. However, there's probably four or five active ingredients that make up 80 percent of those registrations. I think there was something like 100 and -- 160 new registrations for quaternary ammonium products.

You know, so, I think that as far as organizing it, you can organize it by active ingredient and then that can be kind of a batch, like, okay, there's 150 products that are subject to registration review containing this active ingredient and we're going to look at those collectively because they would share issues. And you're going to -- you know, a product may be in more than one consideration because it has multiple active ingredients. But it's going to be looked at because it's subject to review and maybe how you organize it is then by what active ingredients it contains. That's -- I'm just throwing that out as a suggestion of how we might look at this.

UNIDENTIFIED MALE: It's sort of like the current reregistration process, by active ingredient and then (inaudible).

UNIDENTIFIED FEMALE: By active ingredient. But you're looking at a group of products because they're 15 years old.

UNIDENTIFIED MALE: Ray?

MR. McALLISTER: Well, by and large, the data requirements for a registration are levied on an active ingredient basis. That doesn't hold strictly across the board, but then those conditions of registration or the terms of registration are implemented on a product basis, the end-use product label.

So, as Sue said, it's got to be a stepwise process. You start with the active ingredient and that's where you levy the data requirements or evaluate the data requirements and then implement them on end-use product labels.

UNIDENTIFIED MALE: Warren?

MR. STICKLE: A couple of points. By 2006 or by 2008, a number of things will have hopefully transpired by then that will enhance your understanding of

registered products. Reregistration, as we know it, will probably be complete. Tolerance reassessment of the 9,700 will be complete. A review of all of the inerts, the roughly 850 food use inerts will be complete. HPV data has already been collected. Endocrine review will have begun by 2005 or 2006 or sometime thereafter. So, you will have much more data right now than you have.

But in addition to that, you also will have regressed to the point where 158, hopefully, will be coming up by the end of the year and will be going through a process, so at some point in time you'll have an idea of exactly what 158 is.

And I think that's really the key. I think Ray's pointed that out, others have, too. And I think what we're really looking at here is what -- looking at evolving science and data gaps that might exist, depending on what 158 says, and I think that's the principal guideline we ought to be following.

You know, if we get all this stuff done on tolerances and tolerance reassessment and reassessment of inerts, I don't think there's any point in going back and doing that job all over again, especially since it would

have been considered reviewed and completed by the time this program kicks in. So, I don't see why we have to reinvent the wheel.

And there are so many other things that haven't really been looked at, such as the products that were registered after 1984 that you ought to put some kind of emphasis on looking at those -- especially those that neither have -- neither a RED on one hand nor have gone through tolerance reassessment. So, in other words, if you're looking for areas that really haven't had much work on, I think we've come up with a list that would really help define the priorities and the scope of where this project ought to take off.

UNIDENTIFIED MALE: Just so (inaudible) opportunities for easy off-ramp?

MR. STICKLE: No --

UNIDENTIFIED MALE: (Inaudible).

MR. STICKLE: Well, I'm really saying two things.

UNIDENTIFIED FEMALE: Criteria.

MR. STICKLE: First of all, you don't need to redo any of the tolerance reassessments in the way that

you've done them because you've just done 9,700. You've just done roughly 800 food use inerts and completed the work on that and inerts aren't registered products and inerts shouldn't be included in this and you have a separate program already to do that.

But what I am suggesting, though, to turn it on the other side, what should be done or could be done, you've got a lot of products that were registered after 1984 and there was at least three different types of products that come to mind immediately, products that have no RED or no tolerance reassessment. In other words, very little work's been done on them.

And then you have the situation where you have some that have a tolerance, but not a RED and others that have a RED, but not a tolerance. So, you have those really three combinations of different types of products that were registered after 1984 that we ought to put on some kind of priority that makes them start with those first because that's where the review has not occurred, that's where data gaps might exist and that might be where the focus could start.

UNIDENTIFIED FEMALE: Can I just ask -- this is

to Betty, just a clarification. I mean, the agency's reassessing all food use tolerances, not just those that are undergoing reregistration, right? I mean, primarily the focus --

MS. SHACKLEFORD: Right.

UNIDENTIFIED FEMALE: -- has been thus far on chemicals that have been going through reregistration. But by 2006, it --

MS. SHACKLEFORD: It will be all gone.

UNIDENTIFIED FEMALE: Technically all tolerances will have been reassessed. So, the only active ingredients that we would be looking at post-1984 would be active ingredients for which there are no food uses? Would that be correct? I mean --

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: Correct.

UNIDENTIFIED FEMALE: Okay.

UNIDENTIFIED FEMALE: So, yeah (inaudible) that would be correct.

UNIDENTIFIED FEMALE: But there either will have been a tolerance reassessment or a RED for all food use

products.

UNIDENTIFIED FEMALE: The tolerances that are subject to the tolerance reassessment are those that were in place up to '96. So, if you had something established post-'96, it would not have been included --

UNIDENTIFIED FEMALE: Reassessment, but it will be in compliance with FQPA?

UNIDENTIFIED FEMALE: That's right. (Inaudible) that's right.

UNIDENTIFIED FEMALE: And I don't -- like I said, anything registered after 1996, we're not 15 years out anyway.

UNIDENTIFIED FEMALE: Right, exactly, exactly.

UNIDENTIFIED MALE: Cindy?

MS. BAKER: I don't know that I have specific answers for my comments, but I think we're crossing now scope and prioritization. I mean -- and I know it's a tendency that we want to move forward, but I think in the -- one of the things that I think will be real beneficial to stakeholders who are interested in this is having a very clearly defined scope. I think we really do have to spend some time and define what are we -- what is a

registration review? Is it a form that has a checklist like Bob says, and if it is, what's on that, you know? Is it -- and when does the clock start? Is it as soon as the product is registered or an AI is registered? Is it right, you know, as soon as an IRED is completed, is it as soon as a RED is completed?

I mean, I think some of these things might be difficult for us to tackle, but these are the kinds of things, I think, in a public participation process are really critical to get out there to define what exactly is the scope of what we're talking about. Are we talking about any inerts at all? Are we talking about just end-use products? Are we starting just with a batching by active ingredient? And I can certainly see the strengths of that because if you go to just end-use product, you can cross yourself up. I think if you look at an active ingredient, you probably have to start by grouping it that way.

But I think, you know, what are the criteria that we're looking at? All those kinds of things, in my mind, say scope and I think it's critical that we're all on the same page and that the agency clearly defines,

this is what I'm talking about for registration review. Because when I look at it I say, you know, the intent of this was that chemicals didn't sit there for, you know, 20 years and nobody looked at them. You know? The intent was -- to piggyback a little bit on Anne's thing -- there was an update that goes on. Some of that happens through the natural registration process. If you add a new use, there's an update that goes on when that happens or, you know, maybe you submit a new study as a result of a data requirement or something like that.

So, there is some natural updating that goes on. Does that restart the clock then, you know? I think we needed to find some of that scope here so that we're all talking on the same page.

UNIDENTIFIED FEMALE: I think Cindy has really hit an important topic because I think that -- I certainly was thinking in terms of scope being just with chemicals and how do you select and that is more priority. And I think scope takes us right back to Dan's point. What do you have at the end of whatever the review is that you've done? And I think that's probably a very large part of what we need to determine in scope

and I agree that we also need to have set out the selection or -- yeah, how do you -- 15 years from what?

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: And I think those are both -- I agree completely that that's -- you need to start there probably.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Well, I just wanted to first make one comment on what Julie said. We may have several of the -- we'll call them newer compounds that haven't gone through tolerance reassessment because they have food uses. But when you complete a tolerance reassessment, it doesn't -- and you have a TRED, tolerance reassessment -- I forget what the whole thing stands for --

UNIDENTIFIED FEMALE: We already have (inaudible).

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: But in that case, have you looked at the environmental data on that compound or only the human dietary data applicable to human dietary

assessment?

UNIDENTIFIED FEMALE: We wouldn't have considered the environmental data (inaudible). The only thing we would have considered as a part of the TRED would be --

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: -- (inaudible) drinking water contribution.

UNIDENTIFIED MALE: So, something like that might come up on its 15-year cycle and say, you've done tolerance reassessment, so there's just this comparatively smaller piece to do, consider that or --

UNIDENTIFIED FEMALE: That's why I think in that scope thing, if we come up with what is it at the end of the day that you want to have said you have reviewed, then you will get at that.

UNIDENTIFIED MALE: Um-hum.

UNIDENTIFIED FEMALE: I mean, if it's tolerances, then you go down a path and you say, okay, we just finished a tolerance reassessment, you know, six months ago. Nothing -- we have no new tolerances, we have no new data, we have no new explosion of

information, check off tolerance.

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: Environmental, you know, we haven't. So, whatever. I mean, I think we've got to define what that is or I think we're going to get bogged down.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: I just wanted to follow up on Ray's point because I think he's right on target. If you've got something that's had a RED, but hasn't had a tolerance reassessment or vice versa, you don't have to go back and review what you've already done, but you've got a little bit more to go to finish that off. And maybe the registration review can look at those that have not been completed. In other words, there are gaps along the way.

Those that have the most gaps are those that don't have either a RED or a review. And the point is, we want to probably start with something like that and then come back to those that -- that fit in the other categories that I was talking about, not that you have to

redo everything in every one of those categories, but it's a question of when to start and how to create the scope of it.

UNIDENTIFIED MALE: (Inaudible) do you have any thoughts on (inaudible)?

UNIDENTIFIED FEMALE: Well, my (inaudible) comes back to the original discussion that I have to -- I admit, I feel a little bit out of my element here because I'm definitely not a chemical manufacturer or a registrant in any way. So, my input really comes later as far as where the end user issues fit in because that's where I'm seeing the confusion is in the labels and at the lower levels. But I don't know if that's really appropriate for this portion of the discussion.

I mean, I see a real need here for, I think, all the points that are being brought up are critical, that we need to clearly put the scope down and, perhaps, when we define that more clearly, we can see where these other issues -- like the PETA issues and Erik's issues and the other people's. I'm not -- I think, I guess, until we really define this process, where these inputs from these other stakeholders because where the actual registrant

stakeholders fit in, I'm not really sure here. I'm (inaudible) being quiet. But right now, I'm just absorbing trying to see how this all plays into -- you know, where my role is is really at the end, recommending chemicals or not recommending if they're not needed and where the -- you know, there's a lot of confusion at the grower level and there's so much diversity in the labels.

Captan is a good example right now. We have two different products. One has a 24-hour reentry and one has a 96-hour reentry and the growers are constantly asking me can I explain the toxicological basis for that type of a decision. So, I guess that kind of gives the scope of where my perspective and questions are coming from as of that end user level. I want to understand the whole process so that I can give a more accurate explanation at the field level. So, my apologies for not being more profound.

UNIDENTIFIED MALE: Troy?

MR. SEIDEL: I'm in much the same boat. I think my contribution will be later on.

UNIDENTIFIED MALE: Okay. Erik, I think you were next.

MR. OLSON: Yeah. I mean, I guess the question on the table is what is the scope of this process and I think, you know, if you read what the statute says, the scope of the process is reregistration of the chemicals that have been registered. The question that's more difficult is, how are you going to set priorities and how are you not going to waste your time on things that are not worth your time?

So, I do think that priority setting is the more important issue and the scope is sort of established by Congress.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: I was just thinking about that last comment. I agree with the comment down here that label review should probably be a part of the process. I know we talked a lot about data and, you know, possible requirements coming out. But at the end of the day -- as much as I hate to admit it as a product registration manager, by telling you that label review needs to be included is going to add just a ton of work for me.

But being good stewards, I think it has to be

included as part of the process and the agency really needs to come up with a consistent policy from PM to PM and how they're going to review these labels at the end of the day, because as it stands right now, quite honestly, you -- I've seen here recently within the past couple months, just some outrageous requirements coming back from the PMs, stuff that I would really consider not even to be within the legal realm of the agency to recommend to the registrant, and you put on top of that first aid statements, everything that's come out.

I think for consistency purpose to the growers and the end-use product and the end users, it really needs to be considered.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Before we leave that, could I just ask one clarifying (inaudible)? And it's just maybe sort of a technicality, but I want to make sure that I'm understanding.

Under the existing reregistration program, we count the chemical as reregistered upon signature of the reregistration document, RED, TRED, IRED, whatever. But we know (inaudible) complete product reregistration and

that process will typically take anywhere from two to three years beyond the signature date on the RED.

Are you suggesting, as a group, that the agency, in its regulations, include or move the date when we take credit for completing the reregistration review to when product reregistration is completed? So, we would -- let's just say for the sake of discussion -- sign a RED, but that wouldn't be the completion of reregistration review. We would not be able to count until the complete product reregistration. Is that what you're suggesting?

UNIDENTIFIED FEMALE: I think only if you're looking at -- well, I think I can answer your question and make my comment at the same time, and I'm going to go back to something Sue said very early today. She said, we don't need a one size fits all and I'm starting to think that maybe what we need to look at is that we're going to have a process for the registration review of active ingredients and have a process for the reregistration review of end-use products and not necessarily have them -- that one has to be combined with the other.

And that way, you know, you can look at that

active ingredient and its data and its uses. But then you can separately just, on a periodic basis, look at, you know, the scope of end-use products that were registered in any given year, any given time frame and make sure -- you're not going to reassess the active ingredients at that point. You're only going to reassess that end-use product.

You'll say, okay, is this label in compliance, does it meet all of our current labeling requirements? The active ingredient will be addressed when the active ingredients are reviewed, but we're going to look at this end-use product. Does it meet end-use product requirements? And just do that on a periodic time basis and that way -- and to --

(End of Side A, Tape 2)

UNIDENTIFIED FEMALE: -- that way, we kind of get that more leveled out playing field for products as new requirements come in, that the older products will get caught up then, too.

So, maybe we -- you know, instead of trying to figure out how to do both in one process, let's just look at the two different processes.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Yeah, I just -- I want to follow up on Erik's comment because reading this language, reregistration, as a process, was spelled out through a whole series of legislative language which was much more than one major paragraph and several subsections. It has a regulatory endpoint that was dictated by the statutory basis.

As I read this, what this says is you're supposed to put together a process for reviewing a pesticide, but the regulatory process would kick in after that review took place on the basis of administrative follow-ups, procedures (inaudible) requirements of other sections of the law. I don't read this as having a regulatory endpoint other than a review process to determine if a registration has substantive issues or no issues relative to continued registration.

I don't see -- I mean, am I reading it wrong?

UNIDENTIFIED MALE: No. What I'm saying is that registration of pesticides are to be periodically reviewed. The scope of that is that EPA is supposed to review the registrations of all pesticides. That's at

least how I read it. But the -- are you done with your comment?

UNIDENTIFIED MALE: Yeah, I --

UNIDENTIFIED MALE: Because I think I'm -- unless your card is next. But my comment sort of follows up on that. I think that if -- and also on Betty's question. If registration of end-use products is not part of that review and built into it, I'm concerned about the very issue that several of you have raised, like Roberta's issues, which was that you're going to have a lot of inconsistent labels for the same product because they're out there and they were adopted before their review has gone forward.

So, they may have been adopted at different times, and if you don't have sort of a clear -- it may be subsequent in time. But if you don't have it sort of built in that you're going to review the end products and the labels, as part of this process, I think there is a very real risk that you would end up having sort of wildly inconsistent labels for similar products and that kind of thing.

UNIDENTIFIED MALE: The way I look at this is

the information that's on a product label influences how a product is used, what the risks are to human health and the environment.

And as a part of the registration review, the agency has -- the agency, obviously, has to look at the product label, the information from the product label, plus additional information to help it characterize the potential risk, and as a part of that process, decide that either everything is okay, all the risks meet the letter of the FIFRA or they don't. And to make it meet FIFRA risk requirements, you've got to do something with the labeling, you've got to make changes, which includes, in my mind, making labels consistent where they need to be consistent.

Then it just logically flows that as part of the process you have to do the labeling stuff, which that to me means updating the labels, improving them, making sure that there are consistencies where there need to be consistencies, that risk mitigation measures that are necessary meet the FIFRA requirements and are reflected on the labels. And, again, those are consistent across products where they need to be consistent.

So, it seems to me we can't -- the agency couldn't do registration review without getting into the labeling aspects of it.

UNIDENTIFIED FEMALE: My point was when do you count, not whether or not you need to do (inaudible).

UNIDENTIFIED MALE: Right.

UNIDENTIFIED MALE: And, Jay, with that point -- because I don't disagree with what Erik said at all relative to the process. I think you have to look at the end products for consistency in a registration review and that's the major difference between the reregistration process as it's currently situated and what this -- I think this envisions in this process. And I don't disagree that it's two different things.

But, Betty, I'm -- from an accounting standpoint, I mean, that kind of -- that's kind of -- reregistration, in and of itself, is going to end at some point in the future down the road supposedly anyway, and then everything is going to be -- supposedly --

UNIDENTIFIED MALE: (Inaudible) starting in.

UNIDENTIFIED FEMALE: Yeah, right.

UNIDENTIFIED MALE: Starting in at some level,

but that's where -- that's my question relative to whether these -- this single paragraph is intended to totally constitute a brand new reregistration process similar to what's on the books now, which if it is, I don't -- I don't see that in this language.

And that's where I think the scope and magnitude is going to have to be really carefully crafted in defining what registration review is so that we get a clear understanding on that. Because that was under your point, Betty, on when you start counting and when it starts and what you get credit for at the end of the day, or actually, I think more important is, not when you start counting, but when you can count it as being completed, which is, from your perspective, more important.

And that gets to the resource issue and some other things when you're going back to Congress to try to decide how you've set the priorities and how things dovetail into the regulatory process that may or may not kick in after that registration review is envisioned in this session of the law. I think that's what we're supposedly sitting around this table to come up with some

help (inaudible) in this process.

UNIDENTIFIED FEMALE: Yeah, I just -- I wanted to pick up -- before Dan spoke, too. I mean, Erik said this is reregistration. It's not. I don't see anything --

UNIDENTIFIED MALE: I agree.

UNIDENTIFIED FEMALE: -- in this paragraph saying that EPA is required to make new 3C5 decisions. I think it's review and, again, I think that's where you don't bother yourself -- you know, don't box yourself into a process that drives you to come to a 3C5 procedure. I don't think that's at all what this is about. I think it's taking a look at registrations and seeing what, if anything, needs to be done to update or whatever that registration.

So, that's my first point. To the issue of labels, one of the big limitations, I think, one of the lessons learned from reregistration is that REDs, even after they're done, you can have years of delay before somebody gets around to looking at the submissions, you know, from the parties who had a product.

And so, in the meantime, their labels are their

old labels, not the new labels because they haven't been reviewed. But I think even more telling than that is that when products go in for an amendment or a new product is put on the market, I will be very candid with you, PMs are not looking at the REDs, they're ignoring the REDs. They are wildly inconsistent from day-to-day on what they come up with as far as labels are concerned.

The label review process in OPP is broken and to the extent that this program -- but I think that we can't just rely on this program. I think this is a whole separate issue as far as labeling is concerned. But, certainly, consistent labels that reflect the risk decisions that have been made should absolutely be part of this process.

UNIDENTIFIED FEMALE: I guess my point, Jay, is I go back to what I said a few minutes ago. I agree with Erik that how we prioritize and what kind of process we put in place is probably more critical than scope. But I think we have to define the scope. I think it -- I mean, just the discussions that we've had right here, I'm not sure that we're all on the same page. And maybe what might be a good way to do it is to have -- and we've done

this with other committees, have one or two, three people take a shot at laying out what do we see as the scope and bring it back to the full committee later rather than continue to go round and round and round about scope.

I mean, I think we've heard a lot of different comments. But maybe what we could do -- I mean, what we talked about in the conference call was have this meeting, have an in-person meeting before October, and in the middle of that, try to work through some of these details. So, maybe a couple of us could volunteer to work on scope, and at the next conference call or the next email session or however we decide to go on and communicate as a committee, throw out, you know, how about this for defining scope, because I think it's important that we define it.

I think it is important, but I agree that our time might be better spent talking about how do we prioritize, how do we set up an off-ramp, what is -- you know, what is the process for public participation look like or whatever. But I think it's important to define this.

UNIDENTIFIED MALE: Yeah, there's a lot of cards

up. I think we need to be careful -- and, Margie, chime in if we need to. But this group needs to be careful about the structure and whether or not we break into subgroups or not. I don't think that really we should be doing that. But I am in favor of in between meetings, groups collaborating on recommendations, ideas --

UNIDENTIFIED FEMALE: Well, I'm not suggesting forming a subcommittee. I'm thinking of, like, you know, Jennifer Sass and I and Dan, I think, in the CARAT Committee, worked on a presentation that we then brought back to the full CARAT to try to, you know, move us along on an issue. So, I'm -- that's all I'm suggesting, not a formal separate group, but maybe a couple of us take a stab at trying to define it so that we can then try to come to some consensus.

UNIDENTIFIED MALE: Okay. Yeah, I think that's fine. I think that's a good idea. You know, we can only do so much during these one-day get-togethers or even conference calls, which we probably (inaudible) quite as much. And I think those of you who are willing and able to devote additional time in between come up with (inaudible) if you will, for recommendations, ideas, you

know, getting some definition around some of these issues. I think that's great and I realize (inaudible).

Julie?

MS. SPAGNOLI: This is just a quick comment. I think as we're looking at this again, as far as what do we consider complete or done, if we're looking at the end-use products as a completion, we also have to remember that a good -- there's a lot, a lot of products that have more than one active ingredient. And so, if we tie completion to saying, okay, for a given active ingredient, we have to review all of the end-use products with that active ingredient, we'll never be done because you'll never complete, then, the products that have multiple active ingredients.

So, again, I think, you know, it may be beneficial to look at review of end-use products in a different scope than we're looking at review of active ingredients.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: I think there were others who had cards up before me. Mine is just a short comment. When Cindy was talking about having a smaller

group perhaps take a crack at laying out the scope, I think that that's a very good idea, and I think if we decide to do that, maybe we could pose a set of questions to that group so that we could have the scope of the scope before that groups starts.

UNIDENTIFIED FEMALE: Well, that -- I mean, what does the outcome look like, when does the clock start, what is complete? You know, those -- I mean, I think those are the kinds of things that we've been kicking around here, you know.

UNIDENTIFIED FEMALE: And then, you know, if a small group were to take a crack at doing that, then that could be the subject of a conference call.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: So that we could all focus on it. And I think we could have a very profitable conference call if we -- the last one was kind of difficult because we had so many things to talk about. But if we just had the scope, we could get a lot done.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: It's just a scope of the scope --

UNIDENTIFIED FEMALE: Oh, no.

UNIDENTIFIED MALE: -- and then (inaudible) that I think Cindy is right. It seems to me the way to look at this is that whenever the time starts, there is an intervening 15 years and lots of things happen in those 15 years. There are label amendments and new uses and sometimes new standards in the data requirement, lots of PR notices, dozens of PR notices, and now it's 15 years later and lots of just continuities and things crept into the system (inaudible) 15 years and this is the opportunity once every so often, every 15 years, whenever that starts, to make sure that that product is in conformity with all those changes that occurred since the last significant time we looked at it.

If we just have a list of those things, you know, are there new data requirements, are there new labeling requirements, were there PR notices, was there (inaudible) requirements. (Inaudible) checklist and it's yes, yes, yes, yes, yes, you, in a sense, have accomplished a lot of what I think this intends to accomplish (inaudible).

UNIDENTIFIED FEMALE: I have a question.

(Inaudible) I guess for everyone. Talking about the scope, when you're talking about the scope, basically we're asking where you stop, right, Bob, is that what -- you just went through a pretty orderly process --

UNIDENTIFIED FEMALE: We start and we stop.

UNIDENTIFIED FEMALE: But where do you stop? I mean, do you draw an endpoint there or then do you go to another level and start looking at the labels? Is that what you're trying to say?

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: I mean, for scope, you mean just the overarching process and where it starts and where it's completed. That's what we're trying to define, right?

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: I think it would help for this exercise, however we structure it, if we structure it -- we can leave it totally unstructured -- it would help for the entire group to have access to the comments that were submitted on the advance notice of proposed rule making three years ago. That's long enough ago. We can't go to the electronic doc and just download

everything. So -- and it's not a tremendously voluminous amount of material, so we'll just distribute those perhaps as early as this afternoon.

UNIDENTIFIED FEMALE: Actually, that's doable. I have that.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: Great, thanks.

UNIDENTIFIED MALE: (Inaudible). Erik?

MR. OLSON: Yeah, I'm not sure whether this comes under scope, but I wanted to react to -- someone said that they're not sure we need to make another 3C5 determination as part of this process, which is basically we don't need -- do we or do we not need to make another decision as to whether this product complies with FIFRA and the risk standard? And I think, clearly, that's the whole reason that we're here and the reason for this process.

So, I don't know if that's a scope question or what's at the end of the ball game question or what kind of question it is. But it strikes me that that's a pretty fundamental issue that needs to be discussed,

because I certainly view the statute as envisioning that. Otherwise, I'm not sure what the reason for the process is.

MR. ELLENBERGER: Yeah, let me -- before we break for lunch, let me throw out a challenge, I think, that some of you have already done, and that is for a group of you to volunteer to work on the scope of the scope, really come up with recommendations for presenting to PPDC, how you sort of define registration review in terms of the end product, not so much what it looks like, per se, but what is the -- what do you think the agency ought to be looking at? What is the final decision about?

And, again, thinking of -- there's been a lot of discussion about sort of the balance of the focus on the AI versus the end-use products and labeling and tolerances and so on and so forth and sort of work on that. Who wishes to work on that?

UNIDENTIFIED FEMALE: I'll work on it, Jay. How many is that?

UNIDENTIFIED MALE: That's everybody.

UNIDENTIFIED FEMALE: Let me say this, if we all

volunteer to be the subcommittee, that's going to be hard. What I would say is maybe four or five of us or at least represent some different interests here, you know what I mean?

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: And then you'll pick one of us from each group, however you want to do it, Jay. I would never assume who you pick. But then if we emailed it out to everybody, you know, once we did it and then we have our next conference call, this is a major topic of it, then I think everybody gets an opportunity to have some input into it.

But I think if we get, you know, eight people on a committee, we might as well just go ahead and do it here.

UNIDENTIFIED FEMALE: Well, I -- but I think there's people (inaudible).

UNIDENTIFIED FEMALE: That's what I mean, pick something -- pick --

UNIDENTIFIED FEMALE: Because right now (inaudible).

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: (Inaudible) and I don't think (inaudible).

UNIDENTIFIED MALE: So, again --

UNIDENTIFIED MALE: One possible approach, and I hate to suggest more email, but, you know, if you create a list that everybody gets the correspondence on drafts --

UNIDENTIFIED FEMALE: Yeah, right.

UNIDENTIFIED MALE: -- then those who want to can contribute, the others can follow along.

UNIDENTIFIED FEMALE: Right, right. I could just -- right.

UNIDENTIFIED MALE: So, you have a core group, but the core group --

UNIDENTIFIED FEMALE: It doesn't have to be --

UNIDENTIFIED MALE: Well, everybody can be on the list and get all the correspondence. And those who -- a core group are actually putting together the initial proposals and anyone else can chime in all they want to.

UNIDENTIFIED FEMALE: Right. I think somebody's got to take responsibility to write it up and send it

out. I mean, you need to --

UNIDENTIFIED FEMALE: Right. And that may be just the group is everybody who's on the subcommittee, subgroup, whatever it is, and that one person be asked to start the ball rolling.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: That's what we need to do.

UNIDENTIFIED MALE: Do you want to -- do we have a core group now or do you want to think about it over lunch and then talk about it briefly when we get from lunch?

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: That's fine.

UNIDENTIFIED MALE: Okay. Because I do want to make sure that the core group is balanced.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED MALE: I think it's a great idea about the core group as it develops drafts can send it out to the whole membership and then others can add to it or comment.

Okay. Well, let's break for lunch. I think this has been a very productive morning. I know

I've taken lots of notes and a lot of good ideas (inaudible).

(A lunch recess was taken.)

AFTERNOON SESSION

MR. ELLENBERGER: You all should have in front of you a copy of the comments that came into the ANPR a couple years ago that you all asked about before lunch. Vivian (inaudible), who's not here now, made copies instead of having lunch. So, maybe she's out getting a bite to eat now. So, I want to thank Vivian for that.

MS. SHACKLEFORD: Let me just add that Vivian is the agency's lead on developing the implementing regulations. She's (inaudible).

MR. ELLENBERGER: Before we broke for lunch, we talked about the idea of some of you, or maybe all of you, developing a paper -- a white paper -- on scope of the scope, I guess is the coined --

UNIDENTIFIED FEMALE: I just meant that we would talk to the scoping committee.

MR. ELLENBERGER: And many of you raised your hands that you wanted to participate and we want to have a good representative group doing this and I asked you to think about it during lunch. So, what would you like to do? Do you all want to do it? Does one person want to take the lead of actually crafting things and sending it

around as opposed to a small discrete workgroup?

UNIDENTIFIED MALE: I nominate Cindy to take charge. She brought it up.

MS. BAKER: Nominate Cindy?

(Laughter.)

MS. BAKER: Did I miss the important lunch?

UNIDENTIFIED FEMALE: (Inaudible).

MS. BAKER: That's good. I'm --

UNIDENTIFIED MALE: Yeah.

MR. ELLENBERGER: I'm sorry, what?

UNIDENTIFIED FEMALE: (Inaudible) itself.

MS. BAKER: Yeah, if we could set up an email list so we could email it out, that's fine. I'll take a stab at writing something up and sending it out. Where's Erik? Is he going to be all right?

(Laughter.)

MR. ELLENBERGER: Okay, good. So, you're thinking about writing -- taking a stab and sending out a rough draft in a week, two weeks.

MS. BAKER: A couple months.

MR. ELLENBERGER: A couple days.

(Laughter.)

UNIDENTIFIED MALE: I think this can start out fairly simple --

MS. BAKER: Right.

UNIDENTIFIED MALE: -- perhaps just a set of half a dozen principles or a one-page outline.

MS. BAKER: Right.

UNIDENTIFIED MALE: And then begin to fill it in.

MS. BAKER: Right.

MR. ELLENBERGER: Thanks, Cindy.

MS. BAKER: What is today? The 16th? So, how about if I shoot to do it by like --

UNIDENTIFIED MALE: The 18th?

MS. BAKER: No, no.

(Laughter.)

MS. BAKER: The end of that next week, what's that, the 25th, something like that?

UNIDENTIFIED MALE: Yeah.

MS. BAKER: Is that okay? I'll try to get something out by then.

MR. ELLENBERGER: Okay, I look forward to that.

Okay, this is the deadly hour, right after

lunch, so we'll -- we've got a mid-afternoon break and then we will adjourn at 5:00 today. So, for this afternoon, I think we are ready, as the agenda says, to get into discussing and coming up with recommendations for the priority setting process, considerations for -- or recommendations for PPDC on how best to schedule the pesticides for registration and review.

We've already had some of that kind of discussion this morning (inaudible). But now is the opportunity to do that until mid-afternoon.

So, does somebody want to take a stab and jump in?

UNIDENTIFIED MALE: Well, we've had a number of opportunities to talk about the areas where perhaps not a great deal of work already has been done. We've talked about areas where work has been done, but the key points here are areas where work by the agency has not really been done. We're largely looking at the products that were registered in 1984 and thereafter. There are some of those products that will have no tolerance and no REDs and maybe they ought to be at the top of the list, maybe 250 or 300 of them.

But that might -- that number might be high. But there's also another group that -- where they've had a tolerance reassessment, but they haven't had a RED and that would be a second category. And then there's those that have gone through a RED, but haven't had any kind of a tolerance reassessment or whatever.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: No, but I'm -- we're starting to look at priorities and where one might start.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: And what I'm suggesting is that we might start on those products that need potentially the most work.

UNIDENTIFIED MALE: Right.

UNIDENTIFIED MALE: And the area there would be those products between 1984 and 1996 for which there is no tolerance or no RED or a second tier might simply be those where there's been a tolerance reassessment but no RED and then there might be ones that have a RED but no tolerance. In other words, part of the work has already been done in each of those cases. So, there's at least three different kinds of places to start with.

The other thing that I would mention is I think Sue's earlier point this morning, if you're looking for priorities, I think you really need to have a criteria for a -- you know, an easy off-ramp, what types of products do you want to include in there, what are the characterizations of that, what are the criterias of that?

You wouldn't want to spend as much time on a product that's recently been reviewed as opposed to one that hasn't been reviewed at all. So, there's got to be a way of setting and putting forth a set of criteria. Maybe we need a separate discussion on how to put together that easy off-ramp, but I think that's really an important one.

MR. ELLENBERGER: Ray?

MR. McALLISTER: The legislation gives us only one criterion and that's the 15 years. So, there's a direct implication that it's first in, first out. Fifteen years comes past and it's time to do that for that particular chemical. How difficult would it be for the agency to list all of the currently registered active ingredients, and beside each one, put the date of the

most current major review, which might be, first, existence of a RED, TRED, FRED -- whatever those things are.

(Laughter.)

MR. McALLISTER: Or a tolerance reassessment -- TRED would be the tolerance reassessment. Just give us the dates and the type of review and the name of the active ingredient.

UNIDENTIFIED MALE: We could cut -- we could do lists like that different ways. You could do, I think as you're saying, date of initial registration, just that by itself, and then date of reregistration assessment, whatever variation that is, dates of tolerance reassessment. What else? I mean, there's -- I don't know if there's any other process that we've used where you can think of some kind of milestone. I don't know, I can't give you an easy answer. I don't know if it's easy or not, but probably not.

I think giving dates of initial registration are probably easy. That certainly isn't a difficult (inaudible) probably quick on that.

MR. McALLISTER: And the RED documents and all

the various incarnations, they're all posted there, so --

UNIDENTIFIED MALE: Yeah, they're all posted, but I'm trying to think, you know, a flip of the switch versus more manual. I mean, all those are doable.

MR. McALLISTER: Um-hum.

UNIDENTIFIED MALE: But those are options.

MR. McALLISTER: Well, a list like that can be helpful to this group in coming up with the criteria.

UNIDENTIFIED FEMALE: (Inaudible) be much easier to (inaudible).

UNIDENTIFIED MALE: Yeah, I agree entirely. As Ray said, I mean, why make it complicated. Basically put the oldest chemical first and you work your way through the list period. And that (inaudible) but otherwise, why would you even want to do that and you can get into (inaudible). I mean, ironically, the things that you would most like to have reassessed earliest are the things that were reassessed first under FQPA because (inaudible) first criteria. So, there's not really even any reason to go back to those first (inaudible) other than the fact that they come up (inaudible) somewhere.

So, it just seems like (inaudible) from 1 to

1,000 by age sorted on that criteria and there it is.

UNIDENTIFIED MALE: (Inaudible) but it sounds like (inaudible) postdating -- or a predating -- a postdating (inaudible) because those are clearly the ones that will be used (inaudible) strict interpretation of (inaudible) and (inaudible). Then how you (inaudible) is (inaudible). Those are really the two (inaudible).

UNIDENTIFIED MALE: Well, I think what I'm hearing is the presumption that if a chemical and its end-use products have been through either an initial registration sooner rather than later, or reregistration sooner rather than later or tolerance reassessment, those are AIs and products that are less likely to have undiscovered risk issues, so to speak, and if they're current, et cetera, why look at them -- why put them up in the queue right away early on if we just looked at them in the recent past.

UNIDENTIFIED MALE: You've said --

UNIDENTIFIED MALE: And then go back earlier.

UNIDENTIFIED MALE: You said sooner rather than later. Do you mean more recent rather than older?

UNIDENTIFIED MALE: More recent, right.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: So, the presumption is a more recent agency regulatory action on a chemical means it's probably the last -- less risk issues that are -- that we haven't looked at, the data is more likely to be up to speed, so on and so forth. So, we assume that the older compounds have a potential higher risk than --

UNIDENTIFIED FEMALE: No, no.

UNIDENTIFIED MALE: No?

UNIDENTIFIED FEMALE: No, I don't think that's the assumption. I mean, I think that what Ray said and Bob said, you know, what is the criterion that's in the statute? And that's 15 years, that that's the goal. So, what hasn't been looked at in 15 years post-'84, you know. That's starting there, and if you start scheduling based on post-'84 and just take a look at the years, that gives you your schedule. When was the last major review and registration or reregistration decision on the chemical and that drives, you know -- now, there may -- we might want to come up with a hybrid system and -- one of the things I wanted to -- is Carolyn coming back or is Erik coming back?

UNIDENTIFIED FEMALE: Erik went to make a phone call, so he will be back.

UNIDENTIFIED MALE: I think Carolyn is not.

UNIDENTIFIED FEMALE: Okay. Because I know that they had comments where it was obvious to me that they had different ideas on how to select what was coming next, which I, candidly, did not understand. I wasn't quite sure where we were going with that. But, I mean, I think that the absolute place to start is 15 years. If something hasn't been looked at in -- and it has nothing to do with whether or not there are risks or whatever. You have to start there, I think, just because that's what the statute says.

Now, you can refine that, perhaps, but I don't know how you cannot start there.

UNIDENTIFIED FEMALE: They may have no risk concerns at all.

UNIDENTIFIED FEMALE: Absolutely not.

UNIDENTIFIED FEMALE: That it meets -- that, yes, we've reviewed it and we still have no risk concerns.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: (Inaudible) it entails.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: This is kind of a (inaudible) comment. If you're pulling together the data on the different active ingredients, it would be really helpful to know how many products have that ingredient. Because our discussion this morning, we talked -- sometimes we talked about this work as reviewing active ingredients. Other times, we talked about this effort as reviewing individual products labels.

UNIDENTIFIED FEMALE: (Inaudible). When I looked at 1984 through 1990, saying, well, if we get (inaudible) 2005 everything from -- you know, from 1990 (inaudible). And I think (inaudible). And I think (inaudible) product that is still active (inaudible) product. I think (inaudible) on the order of 800 or 900 (inaudible). And, again, there is a lot of active ingredients, but if you look (inaudible) probably a handful of active ingredients that (inaudible) 100 of those products and, you know, there's a whole bunch of certain active ingredients and another (inaudible). That -- I mean, that (inaudible).

UNIDENTIFIED FEMALE: Yeah, yeah.

UNIDENTIFIED FEMALE: (Inaudible) make available what I (inaudible).

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Let me see if I can remember what I was going to say. Oh.

We have a time criteria and the only place I could see where we might need to worry about additional criteria for prioritizing a smaller group might be in the situation where you have -- well, we're starting out and we could argue or it could be argued that there's this group that's overdue because they're past the 15 year date and, therefore, we may need to prioritize within that group, or within a given year, you've got 50 or 80 that come due for reassessment or review within that year and some need to prioritize that.

But I don't see priority as a really big worry. If most of the work is done, it's a five-minute exercise. If there's a lot of work that needs to be done, maybe it's a couple years. If you go through in chronological order and just -- well laid-out criteria for what needs to be done, the easy ones get checked off real quick and

the others get the attention they need.

UNIDENTIFIED MALE: Well, it sounds like it's almost like a priority system sort of by your -- you bite off a year's worth and then in a work plan for any given year, there is some level (inaudible) triage and you hope that there's certainly -- there's certainly a good percentage that are going to be relatively easy to do, straightforward and a relatively small number, small percentage that are a little more complex.

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED MALE: I mean, I don't think it would be that difficult to actually develop a 15-year work plan. I mean, obviously (inaudible) the time, but you can define the universe of what has to be done and how many (inaudible) and any new registrations (inaudible) after (inaudible) on that list, so there won't be (inaudible) to be reviewed until after 15 years and then -- I mean, the only other issue I'd say in terms of scheduling would be probably the '84 to '90 -- the '84 FQPAs probably will require a little more work than the post-FQPAs, you know. So, you have to throw that math in because (inaudible). (Inaudible) you're almost going to

end up getting (inaudible) first by doing it that way (inaudible).

UNIDENTIFIED MALE: The question is, where do you start the chronology? And you could start it probably beginning in '84 and then working your way up.

UNIDENTIFIED FEMALE: Or '85 is the post -- the post-'84 registration.

UNIDENTIFIED MALE: Um-hum.

UNIDENTIFIED FEMALE: Registrations beginning in '85.

UNIDENTIFIED MALE: Well, it's really --

UNIDENTIFIED MALE: November of '84.

UNIDENTIFIED FEMALE: Oh, okay.

UNIDENTIFIED FEMALE: I guess I have just kind of a general comment and it's supportive of what, you know, you've already heard, which is that I think, you know, one of the take-aways I had from all of our discussions before lunch was that we've got to be really careful not to over-complicate what we're doing here, because we could very easily make this a full-blown, you know, reregistration, FQPA type thing and I don't think that was the intent of the statute and I don't think

that's the best way to get it done.

So, I guess just kind of distilling what we've talked about, I think keeping it as simple as possible is probably the highest priority we ought to do, which is, you know, the statute is pretty clear. Every 15 years, the pesticide registration should be reviewed. So, I think using that as a time line to at least give you a sense of what is the universe that you're looking at, because I think if you use that cut-off, you're going to get a pretty good sense of what the universe is, and then when we get into the discussion about process and we start talking about, you know, things that have just been reviewed, has anything changed, the easy off-ramp, all those other kinds of things that will help you weed through that list, that it will probably become much more manageable.

But I think a key factor that we've got to think about and I thought about even when we started talking about scope, is that we've got to be very careful that we don't make this out to be something more than it was ever intended to be.

UNIDENTIFIED MALE: How about the issue of

chemicals -- chemical family -- that may not be the right term -- but when you think of the current reregistration process and we've developed (inaudible) as required by FIFRA. We've got chemically similar -- we've got chemicals of similar chemistry, related chemistry (inaudible) relationships between data sets, maybe use patterns and those don't always get registered sequentially, but could be years apart.

I guess what I'm thinking about is the potential issue of -- if we're just going strictly chronically, that may get the agency into revisiting and revisiting some of the same kinds of issues and data within this chemical family, which I -- which can complicate stuff.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: Well, but then we're dragging stuff out all over again, it's not the same people maybe and (inaudible) reinventing.

UNIDENTIFIED MALE: Are there any criteria that you can set out as a threshold (inaudible)?

UNIDENTIFIED MALE: Well --

UNIDENTIFIED FEMALE: That's what we would -- yeah.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Are you talking about something different from the common assessment groups or common mechanism groups or is that what we're talking about?

UNIDENTIFIED FEMALE: No, for instance, I think what you're talking about here is, for example -- and Julie said some of the '84 to '90 chemicals are quaternary ammonium compounds and there are, you know, a couple hundred quaternary ammonium compounds and they've been put, basically, into two cases in reregistration and the kind -- and the data package is basically bridged for most of those substances. There aren't 100 or 200 data packages. You know, you bridge to those. And I think that that is clearly -- and I think these are the kinds of things we do need to think about.

These quaternary ammonium compounds come up because there were two new ones that were registered '84 to '90 and they bridge to what's already there or even if they didn't, but they probably did. You know, and you're still reregistering that whole case, we should only be looking at them at one place, you know, and so -- and

where you have various salts or you do have related families, I think absolutely -- you know, the goal is 15 years.

I think the simplest way to undertake this is to take the first cut at 15 years, but then I think you have to make some intelligent decisions and certainly, in terms of these chemical families, that is a terrific way, I think, to make this manageable and I think we're barking up the wrong tree if we would look at each one of those quaternary ammonium compounds, for example, again as an individual chemical that needs to be addressed individually.

UNIDENTIFIED FEMALE: I think that's a very good point.

UNIDENTIFIED MALE: I've got a comment on a much narrower focus than that. But looking strictly at the common mechanism groups, which are identified for the purpose of tolerance reassessment, those are being done now. They will have been identified. The only -- everything up through FQPA falls under tolerance reassessment. So, their common mechanism groups will identify any brand new chemistry registered since then,

by definition, has to comply with FQPA upon initial registration.

So, from the dietary perspective and cumulative risk assessment, I don't think we're going to find any issues there. Now, this is -- the quaternary ammonium issue is something broader and could spill over into other areas beyond dietary risk assessment for other groups besides those quaternary ammoniums and certainly we need to make some intelligent decisions. This might be an area where we could look at ways of encouraging, shall we call it, forward compliance, you know.

Chemical A might be up for registration review this year and mine came along 10 years later and it's the same chemical class or family, I might take a close look at --

(End of Side B, Tape 2)

UNIDENTIFIED MALE: -- when my turn comes up.

UNIDENTIFIED FEMALE: (Inaudible) help me with this thought. When we see lists that we'll eventually be looking at, there may be reasons to group things by use, too (inaudible), but from the user's perspective. I'm not saying that we should think about doing that, but I'm

saying we want to consider that when we see these lists. There may be reasons to do that.

MR. ELLENBERGER: Erik, you just came in. We've been talking about different strategies for priority scheduling (inaudible). (Inaudible) really obvious would be to do the oldest first (inaudible) useful to know what the total universe is. Are there other issues that sort of complicate (inaudible)?

I think we would need to look at closely related chemicals and somehow sort of be smart about doing that so there is (inaudible) efficiency and we don't get into reinventing -- reassessing -- people change, policies change, things are involved (inaudible) could be problematic (inaudible) chronologically (inaudible).

UNIDENTIFIED FEMALE: (Inaudible). I really think we need to (inaudible). (Inaudible).

UNIDENTIFIED MALE: Jay, I think the point that you were making is a good one. At some point in time, if the agency has made a determination that there are, in fact (inaudible) however you want to structure that and that you've used that for either tolerance reassessment or an FQPA reassessment or reregistration, in other

words, if you've already grouped certain chemicals together, it wouldn't make sense -- it would not make sense to come back in registration review and then break that all apart. You've already established a group, a cluster or a family.

I think you need to -- you know, again, it's setting priorities. Where you put it, I'm not suggesting that. But I think you ought to keep that group, cluster or family together because we've already made a determination that it is a group, a family or a cluster, you ought to continue with that concept.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Exactly what Warren said.

UNIDENTIFIED FEMALE: I agree, also. I would think that when the reviewers are looking at a different group of compounds, there's a certain learning curve. Just, for example, carbamates, you're going to be thinking of a carbamate rather than why you need to go back to that. But could it also be tied in with a chronological where -- maybe that's what you're all saying -- when you look at the list, you start at the beginning and you find the chemical that is

chronologically ready, but then you realize that there's a bunch more and so then you just (inaudible) those. So, you're kind of doing it chronologically, but the chronology is a trigger then for that group.

So, once you start working on that older compound, if you see later on that there's more in that chemical class coming, that you would address those all in the order -- you would address those all at the same time. So, you'd actually be jumping ahead in that chronological order, but you're still using the chronology as a basis for doing that. I mean, you're looking at the oldest ones first, but then pulling in others that are related to expedite moving through the list.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Right. And then can I just address Theresa's comment, too, real quickly? I wanted to say this in the beginning in that I think I'm feeling consensus from talking to people individually and my own feelings and all about the end-use issues here. I'm thinking, and this is just (inaudible) doing the scope of all this to also that it almost seems like these

label and end-use issues really need to be separate from the actual nuts and bolts reregistration issues that the registrants are going through. I'm not invalidating those end-use issues because that, in truth, is how the chemicals get put out in the environment and all that. I mean, that's really important.

But we've got some real major issues regarding the labels that aren't tied into the legislation process. But I don't know how we can address these logically in the actual steps until we have the registrant's aspects, too, defined and then looking at finding how those products get disseminated into the public health or agriculture or whatever the final uses are, needs to be looked at as somehow a separate issue that feeds back because the label issue is huge, from talking with Theresa and what you said about uses. We have so many problems and issues with that.

I don't want to get long-winded, but I'll tell you one simple thing that is a good example. If a chemical doesn't have an REI, if it's zero, that doesn't have to be stated on the label. There's nothing about the REI that goes on the label. It only has an REI if

there is a stated REI interval.

So, when I'm working with the growers and I'm trying to make environmentally compliant recommendations, the first thing that they want to know is the REI. Well, since the REI is not stated in the same place on all those labels, I spend so much time going through them over and over trying to find that REI when there may not be one. But if it's zero, the zero should be on that label so I immediately know it's zero instead of having to go through over and over again and worrying that I missed it, you know, that it's somewhere in there.

So, not to get long-winded, but that's just a quick example that that's just a whole new section that needs to tie into the registration process. I don't know if we need to have bogged down the whole thing with --

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: What's that?

UNIDENTIFIED MALE: There should be an REI (inaudible).

UNIDENTIFIED FEMALE: Even if it's zero.

UNIDENTIFIED FEMALE: No, what she's saying is there may be an REI of zero, but it's not stated on the

label because it's zero.

UNIDENTIFIED FEMALE: Right, it doesn't have to be stated.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: Yeah, good point. (Inaudible). No, that's fine. Well, I guess I'm (inaudible) exploring Theresa's question about use patterns and -- this is not a new issue. It actually came up -- I think in the initial registration process about should the agency focus on all corn herbicides at one point or all -- you know, whatever, for a use pattern. And we didn't for a number of reasons. We didn't go that direction.

But, again, we were trying to think outside the box, you know. You clearly heard this morning the sort of recommendation that the agency not reinvent, if you will, the current reregistration process, but think about making it more efficient, more robust, more complete, more timely and trying to think outside sort of the old paradigm, if you will. Is there any value in looking at group (inaudible) pattern?

UNIDENTIFIED MALE: I'd like to (inaudible).

UNIDENTIFIED MALE: Sue, you had your card up first.

MS. CRESCENZI: Erik had his up.

UNIDENTIFIED MALE: Erik?

MR. OLSON: I think it's sort of a first principle question for the agency because there are various approaches that you could use. One would be just use the most -- to put first in line those chemicals that have the most stale determination, you know, from 15 years ago. I mean, that would be one approach. I don't hear a lot of people saying that's the best idea, but it's certainly one approach.

Another approach would be to take the classes where there's commonalities of data and commonalities of toxicity information and so on, which is sort of the tolerance reassessment approach, and another approach might be to look at uses, you know, say the corn herbicides, let's look at all the corn herbicides and save cherries, you know, or whatever, tree fruit or something.

And the other potential approach would be a sort of worst risk first approach, which is theoretically what

EPA was intending to do for the tolerance reassessment. And the last approach that I want to just propose out there is to address those classes of chemicals where we know there are whole sets of issues that have never been considered and recent times for them. So, they might be the chemicals where there's been a tolerance reassessment, but there's been no environmental review in the last 15 years or whatever, and all those have merits. All those approaches, I think, have some merits and demerits.

I'm of the personal view that it makes sense to try to have a risk-driven approach where the agency makes its highest priority addressing those chemicals that have either eco or public health risks that might rise to the top, addressing them early on in the process and probably doing that by class. But having said that, those decisions aren't always easy early on and I also am very sympathetic in situations where you have, say, a corn grower or a specific tree fruit grower or whatever that wants to know which product is best, which product presents the least risk, and if the agency says, well, we'll get to that one in 10 years and everybody switches

to that one and it turns out that one is much worse, have we really accomplished anything?

So, I would tend to suggest a risk-driven approach as sort of a first principle and then figuring out how we get to those chemicals that haven't been revisited where we think there may be issues that -- where the database -- the decision is fairly stale sort of at a later point.

UNIDENTIFIED MALE: The current registration process is already a risk-driven approach. And even those cases where you had similar chemistry that's not on the same time table, in a smooth-running process which, say, eventually would get to that newer chemical you will look at that's similar to something registered five years previous, will have taken into account what you know about that previously registered similar chemistry. If you depart from the chronological schedule and establishing the priorities, you're going to fall behind and you won't leave time to reregister some that will pass their due date, so to speak. (Inaudible) and you will not be keeping up with what the Congressional mandate is.

UNIDENTIFIED FEMALE: Potentially, it seems like you would run into that problem if you're going to group things, too. Although I think the grouping is probably the appropriate way to go. But I think that the same problem runs into -- you run into the same problem.

I think maybe a combination of approaches -- I agree with Erik, it should be -- you know, we should be looking at it from a risk standpoint and maybe we go through this first and pick out if there are some obvious ones that we need to do first, those need to be done first, and then move at it from a chronological standpoint. You know, I can't -- it's not going to be easy to pick those out, but there may be a few obvious ones that we say -- you know, like OPs or whatever, you know, where you say, gosh, these are really ones we need to look at and then (inaudible).

UNIDENTIFIED FEMALE: Um-hum.

UNIDENTIFIED MALE: That's part of the problem. What's (inaudible). I mean, the riskiest things were dealt with in tolerance reassessment and, I mean, there's sort of a logic to it (inaudible) because those are (inaudible) the standard views to evaluate those

(inaudible) registration.

UNIDENTIFIED FEMALE: I know.

UNIDENTIFIED MALE: (Inaudible) and then the next kind of group up are the early FQPAs (inaudible) by definition (inaudible) process (inaudible).

UNIDENTIFIED FEMALE: But the tolerance -- would the (inaudible) for tolerance, would they have looked at the ecological impacts as well as part of that?

UNIDENTIFIED MALE: Some of them.

UNIDENTIFIED FEMALE: The IREDs. It depends.

UNIDENTIFIED MALE: It depends is the answer.

UNIDENTIFIED FEMALE: Well, I think, again, we need to look at, I think, what are we reviewing these products for because -- and I'm kind of -- I agree with Ray, you know, if you start trying to do it too many ways, you're not going to meet the statutory requirement. I think the statutory requirement is, does that individual chemical meet the requirements -- continue to meet the requirements for registration. And, you know, which would be are all the data requirements filled?

I think by going chronologically you're meeting the letter of the law because that's what it's stating is

to review those every 15 years, to review the registration. It's not saying necessary that to look at the universe of chemicals and decide what's riskiest, it says review of registrations.

I think to follow what the law says that we just need to look at it chronologically and say, does this chemical meet the requirements for registration or are there deficiencies; either are there deficiencies in data or are there deficiencies in, you know, some type of risk mitigation and address it that way. But I think if we start trying to get too many different ways of categorizing and lumping, you know, or grouping things, it's going to get way too complicated.

UNIDENTIFIED MALE: Troy?

MR. SEIDEL: Thanks, a couple of points. I guess in looking at the statutory language and the 15-year obligation, it seems to have two implications. One is that it's a 15-year cycle, but at the same time, for chemicals that haven't been looked at in 15 years, EPA seems to have an obligation to give those some level of priority. If they haven't, if they don't have a TRED or a RED or an IRED or really anything in that period of

time, so sometimes it seems like the simplest interpretation is sometimes the one to go with to an extent.

But I also -- I do favor what some previous speakers have said with sort of a hybrid approach and to the greatest extent possible, beginning by grouping chemicals as much as we can. I like the idea -- you know, I think it would be interesting to have a list just based strictly chronologically, but also, if we can, take advantage of the groups that have been established during tolerance reassessment and not reinvent the wheel. It certainly would streamline things quite substantially.

So, grouping first and then my suggestion would be to set the clock, as it were, based on the most recent substantive review of any chemical within a group. So, if you have something that went through tolerance reassessment in 2001 and you've got 50 chemicals in that group, set the clock in 2001 for whatever that category is and then you don't have to deal with that for 15 years, and then work backwards to the least recent reviews, be it of an individual chemical or a group, and then start there and work forward. That seems to cover

the grouping issue and also hopefully not complicated things unnecessarily.

UNIDENTIFIED FEMALE: It sounds like you're saying don't figure out what you're going to do first, figure out what you're going to do last and then let it --

UNIDENTIFIED MALE: Yeah. Figure out what you've done most recently, work backwards and then move back up the list.

UNIDENTIFIED MALE: In your argument, if we started tomorrow in our new program, we'd put on a very -- we'd put on December 15 years from now a new active ingredient we just registered yesterday.

UNIDENTIFIED MALE: Right.

UNIDENTIFIED MALE: An issue that we often hear about from registrants and growers is --

UNIDENTIFIED FEMALE: That's all right. Finish (inaudible).

UNIDENTIFIED MALE: Oh, sorry.

UNIDENTIFIED FEMALE: I'll get to it, go ahead.

UNIDENTIFIED MALE: Is sort of a level playing field. If we -- in programs in the past where we've done

alphabetically, chronologically, whatever, the issue of, well, we've got to change the label for my product but not my competitor's product for the same uses. But at the same time, I'm also hearing you all talk about, well, sort of the chronological sort of hybrid kind of thing of identifying some higher risk or classes of compounds and (inaudible) them up. Doesn't that create the level playing field issue for you all?

UNIDENTIFIED FEMALE: It does.

UNIDENTIFIED FEMALE: What I was going to say is, I think that some of these things that we're talking about -- and I -- I steal Carolyn's comment from earlier, I don't mean to sound Pollyanna-ish about it. But I think a lot of these things you're taking care of right now through reregistration. I mean, I think if we're really optimistic and we think we can get this registration review thing going, you know, in a year or even in -- you know, really get it going, get a process, get things going or whatever, a lot of these higher risk, older chemicals, you're going to have a big chunk of those out of the way.

And when you get to -- when we start getting

into talking about the process of what you're going to do, you're going to go, okay, organophosphates, you know, I just finished Imadan and I haven't been allowed to do anything else to it, so nothing's changed since you've finished it, you know, two or three years ago. So, why would you go through the whole thing again?

So, you're going to get some of these things that people are worried about as being the higher risk things. Certainly, not all of them are done, but I suspect within a year and two years, a big chunk of those are going to be done. I think some of this problem is going to go away by itself and that we should really, you know, go back to the simplistic approach of what this is, and I think Julie hit it on the head, it's a registration review. Does the registration still meet the standards to be registered? And then we'll go through the criteria of, you know, what does that mean and check it off and when was it done last and all of that kind of thing.

So, I think having this 15-year chronological start be your starting point is the smartest thing to do because then you're going to pull in -- because even if you take the organophosphates, you know, if you take a

class, for example, that you've grouped like that, you know, the first one was -- maybe it had its IRED in '98 and the last one, it might be, you know, December of 2003 or whatever, let's just say that. You've got a five-year span within that. And what's happened to every one of those may or may not be the same in there.

So, even as you start going through those, you're going to have to go through whatever that criteria is that you select for, you know, what meets registration review and go through it. And some may go off real fast and some may need a little more work. But I think it will -- I think it will play itself out if you look at it like that. And this level playing field thing is a for real issue.

I mean, that's an absolutely for real -- if you're talking about, you know, not just as registrants, you know, dealing with a competitive product. But if you're talking about the apple industry and you have three products that you use for codling moth and you used one early and you used one late and you hammered one of them or you lose one of them, it impacts what happens there, dramatically. So, I think those issues are kind

of for real.

So, I would say, don't lock yourself into it, has to be strictly done chronologically or strictly by group. I think you're going to have to play with this a little bit and let it evolve like we have done with, you know, the tolerance reassessment process.

UNIDENTIFIED FEMALE: I think we -- I think it's -- the level playing field issue is one that we have to be sensitive to the fact that if we do, say, okay, basically we'll let the 15 years drive, that a lot of companies are going to have real problems with that because that's the continuing issue. Oh, gee, if my label has been looked at more recently, my product's been looked at more recently, I have all kinds of prohibitions, you know, that folks who haven't had a label looked at in 10 years don't have. So, I expect that we'll get pushback from a lot of registrants on that.

And, of course, the way to solve that would be to approach it from uses, and I just wanted to get back to Theresa's comment about uses. But I think there are a couple problems with using uses, first being that it's

really not consistent or it's certainly not contemplated in the statute. I mean, a 15-year review was based on the registration, not on, you know, use. So, I think that we have that first underlying problem.

The other thing is, in Europe, the Biocides Pesticide Directive is use driven. And so, what you do is submit a dossier and risk assessment and whatever for a particular use for a chemical and everybody else with those uses is doing it at the same time. But, unfortunately, so many of these chemicals are -- or fortunately, are multi-use. So, then a year later, you have to submit perhaps additional data if, you know, you have to do a different kind of risk assessment or whatever. You know, so you're addressing the chemical in a piecemeal fashion and I think it's inconsistent, among other things, with what the requirements are for FQPA where you take a look at the aggregate exposure even to the chemical.

So, I think there are some real -- I mean, again, that might be one of those additional criteria that may drive some selection sometime. But I think it would be difficult to use it as a major selection point.

UNIDENTIFIED FEMALE: I didn't mean to suggest that it be a first consideration, but that it should be considered as a consideration when refinements are made to the list, you know, so that we could be open to that.

UNIDENTIFIED MALE: Well, it sounds like -- I don't see cards going up -- that we're pretty much done discussing these issues. You want to see --

UNIDENTIFIED FEMALE: Until we see something.

(Laughter.)

UNIDENTIFIED MALE: What was the answer? I didn't -- I missed the answer.

UNIDENTIFIED MALE: I don't think we have an answer, but it sounds like, you know, we're done as far as there is to go with that, with what we have.

UNIDENTIFIED MALE: Do your databases, lists of chemicals' active ingredients have any tags on them?

UNIDENTIFIED FEMALE: You mean like fungicide, insecticide or --

UNIDENTIFIED MALE: Well, like --

UNIDENTIFIED FEMALE: I think he's saying like organochlorines, triazines and --

UNIDENTIFIED MALE: Yeah, organochlorines,

triazines --

UNIDENTIFIED FEMALE: The chemical fact sheets usually say (inaudible).

UNIDENTIFIED FEMALE: Yeah, but that's not --

UNIDENTIFIED MALE: I'm looking --

UNIDENTIFIED FEMALE: He's looking for a way to sort. Can you sort it that way?

UNIDENTIFIED MALE: I'm looking for a way to sort, yeah.

UNIDENTIFIED MALE: I don't know the answer to that. We just went to a new computer system called OPEN (phonetic).

UNIDENTIFIED FEMALE: Now you'll have a disaster. You won't be able to get anything you want.

UNIDENTIFIED MALE: I just had a demo on it. I was blown away. I thought it was excellent.

UNIDENTIFIED FEMALE: Yeah, but it will be two years before it really works.

UNIDENTIFIED FEMALE: Right.

(Laughter.)

UNIDENTIFIED MALE: I don't know. It's been in the pilot stage, you know, so --

UNIDENTIFIED MALE: See, if a chemical --

UNIDENTIFIED MALE: I don't know. I'm not familiar. There might be a way of tagging --

UNIDENTIFIED MALE: If a chemical grouping code or name could be added to this list, that could be helpful. I wouldn't delay the list if that's a major undertaking to add that, but it's a consideration.

UNIDENTIFIED MALE: Well, are you saying that the group is not ready with recommendations for PPDC until you see the list? I'm not -- we don't expect this group to have recommendations out -- here is the exact order for the chemicals.

UNIDENTIFIED FEMALE: Let me help you out a little bit on that one, Jay.

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED FEMALE: Because I think we can develop that list relatively quickly within SSRD and, frankly, we might be able to get it off -- maybe not as quickly as you do by the 25th, but certainly by the following week. And if anything's tagged in the OPEN databases, we can certainly with IRSD to see if there's a way to do that. So, we'll try to pull as much

information as we can together within the next couple of weeks. Bear with us if it's not absolutely perfect. There's been a chemical or two that may not have been included, but we feel certain that (inaudible). But I think we can pull together most of that.

UNIDENTIFIED MALE: Jay, I wonder if we couldn't at least present a couple, three options of different approaches that might be taken to setting priorities. To be honest, I'm just beginning to think about this. But, you know, there may be different ways to do this that we need to fully discuss.

But I think without presenting PPDC with any options at all, it's going to be hard to have -- I mean, I think we're all sort of feeling around this issue and, you know, I think a hybrid approach is inevitable, like Troy was saying, that we're not going to have just a clean chronological approach because that doesn't make sense. But maybe a hybrid of that plus something else. I don't know.

UNIDENTIFIED MALE: In addition to a purely chronological list, I'd just like to make a specific request or just say, for my own mind, it would really

help me to wrap my mind around, it's one thing to say we have 2,000 AIs. But once they're grouped, just to see what the number becomes, does that get slashed to 1,500 or -- and if we can somehow group it based on the groupings that have been used in tolerance reassessment or elsewhere and have some indication there chronologically within a group, what's the most recent substantive assessment that a chemical's undergone and be able to look at it in that way, I think that would really help to inform some of the decisions that are made for recommendations.

UNIDENTIFIED FEMALE: Well, I think what we're talking about here is -- and, again, what I would envision is that we put some of these thoughts down, you know, and then have -- you know, people have a chance to think about them and massage them.

But I think what we really have done here today and what we need to capture, at least as a first draft of anything that we might make as a recommendation is, start with 15 years, but there are a number of other factors that also may end up being considered and that would be if there's a particular risk issue, if there's a

particular use area that's a problem, groupings, you know, what -- and I think, you know, we need to get a draft down of some of the things we've talked about today and then give everybody an opportunity -- I mean, I think this is a really good initial kind of crack at this and now we just -- everybody needs an opportunity to think about it and refine it.

I nominate Ted.

UNIDENTIFIED MALE: I nominate Sue.

(Laughter.)

UNIDENTIFIED FEMALE: I think we also have to remember that this is not the only mechanism by which label changes can be instituted or, you know, issues can be -- right in there it says, nothing in this subsection shall prohibit the administrator from undertaking any other review of the pesticides. So, you know, such is the issue that you brought up with (inaudible), that doesn't have to wait or go through this process. I mean, that would be addressed through a PR notice or some other mechanism. So, I think we can't look -- say we got to figure this out because this is the only way we're ever going to correct anything that might be wrong.

So, I think that's -- again, I think the goal of this is let's look at these products periodically and make sure that all their -- you know, that the house is in order.

UNIDENTIFIED MALE: Ted, you had your card up, maybe I missed something. Do you really have --

MR. HEAD: No, I agree with Sue. I think we need to get it down somewhere to what we're doing with scope and then put it out.

UNIDENTIFIED MALE: Yeah, I agree. You know, one of the charges of this workgroup is to come up with recommendations for the PPDC, for how to prioritize scheduling. I also appreciate having the full list and maybe some kind of grouping, if you will, of the universe can be helpful. I would submit that at least getting down on paper some of these very general recommendations we talked about, I think I'm hearing consensus on anyway. There are no major -- no one is voicing major disagreement with -- guess that's why they call it a hybrid process.

So, I suggest that somebody take a stab at putting it on paper and sending it around.

UNIDENTIFIED FEMALE: I'll do that.

UNIDENTIFIED FEMALE: And, you know, just one thing. If we can't generate a current list of some of the existing groupings that EPA has used, we could still look at the four reregistration lists, you know, Lists A, B, C and D, because if you look at those, those have families, you know, to some extent. I mean, it may not be the end-all/be-all, but at least it's something if we can't get something more current.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Just a thought about flexibility. We seem to be agreeing that some flexibility is going to be needed in crafting a priority list. But it's also very important that once the agency determines how it's going to craft a final list, that it needs to be done with some assurance, you know, that it isn't going to change a great deal. We need to feel comfortable that it's -- that the way it's laid out in the schedule, how it's laid out is what will be followed so that we can all then do what we need to do next.

UNIDENTIFIED MALE: (Inaudible) relatively stable.

UNIDENTIFIED FEMALE: Yes.

UNIDENTIFIED MALE: Minimize the number of shifting things around, particularly in the closest years.

UNIDENTIFIED FEMALE: Well, on that point then, I mean, it's pretty difficult to forecast out 15 years.

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: So, maybe one of the things that we want to think about is breaking this into -- instead of trying to come up with 15-year schedules, to come up with schedules for shorter periods. I just throw that out because, you know, I think trying to forecast 15 years, inevitably, you're going to have some problems.

UNIDENTIFIED FEMALE: Definitely.

UNIDENTIFIED MALE: But if you can forecast five years into the future, that gives registrants some predictability, some stability in what they can plan for. Next year, you get the sixth year, which is then the fifth year in the future, something like that, so you don't wait five years and do another five years scheduling.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED MALE: Maybe five years isn't the right interval, but some interval of several years into the future in terms of planning and scheduling.

UNIDENTIFIED FEMALE: This isn't -- I don't know that this is the right place to inject this, but I think -- I mean, the intent, as I understand it, is that every 15 years, this is an on -- so, it's not like at the end of 15 years we're done. So, we have to, I think, be cognizant of what we put in place here is that, you know, if we take -- you know, say certain ones have to be done by 2008. Well, then we know again they've got to be done again in 2023 and 2038. You know, it's kind of a leapfrogging thing there. So, there -- I'm not saying we need to figure that out for this process, but we ought to be cognizant of that fact that that's in there as well. You know what I mean?

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: Because I think that might impact some of how you look at this priority.

UNIDENTIFIED FEMALE: I think we have (inaudible) put in the regulation as well. I think we

have to have -- it's going to be a hybrid (inaudible).

UNIDENTIFIED FEMALE: Right, a process. Right.

UNIDENTIFIED FEMALE: (Inaudible) just about the 1984 to 1990 (inaudible).

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED MALE: If there are ways of grouping chemicals for the registration review, whether someone's moved ahead in the schedule or waits a few years in the schedule to meet the particular class, eventually you've got them on a 15-year schedule.

UNIDENTIFIED FEMALE: Exactly, right, yes.

UNIDENTIFIED MALE: And keeping in mind that the original list, whatever it turns out to be, the order won't stay -- it's not a stagnant list 15 years -- every 15 years chemicals are getting canceled, products are getting added, new AIs are getting added.

UNIDENTIFIED FEMALE: Issues change, yeah.

UNIDENTIFIED MALE: So, there's a constant -- or a flux, if you will, and you all may want to think about recommendations for how the agency should deal with that. Is it as simple as -- well, if one drops out, all the products drop out, the next one just automatically moves

up in the schedule. I'm not ready for it yet, I thought it was going to be next year and now you're telling me it's this year. Or if we register a new active ingredient and the products that -- that just automatically go at the bottom. I wonder if it's -- again, within a family that's up higher -- so there is that kind of flexibility that we would need in dealing with those (inaudible).

UNIDENTIFIED MALE: I wouldn't see moving things up in the schedule just because something else dropped out. (Inaudible) requirement.

UNIDENTIFIED MALE: No, I'm just saying --

UNIDENTIFIED FEMALE: But I also think --

UNIDENTIFIED MALE: -- (inaudible) do so many a year.

UNIDENTIFIED FEMALE: I mean, let's talk reality. Erik won't like to hear this. But I have never seen us meet a schedule. (Inaudible) dropped up and it moved up, it's probably still two years behind.

(Laughter.)

UNIDENTIFIED FEMALE: That's so optimistic.

UNIDENTIFIED FEMALE: But that's a problem, I'm

sorry to say.

(Laughter.)

UNIDENTIFIED FEMALE: (Inaudible) need to worry about it a lot.

UNIDENTIFIED FEMALE: Yeah, maybe we need to focus our energies (inaudible).

UNIDENTIFIED MALE: But the point you were making --

UNIDENTIFIED FEMALE: I know what your point is. It's a process point that I think has to be -- we've got to be cognizant of it. But I don't know that it's a real problem.

UNIDENTIFIED MALE: The point, also, you're making, Jay, is once we start this registration review process, at whatever time we start it. If we, in a collateral way, approve a new -- a new AI, we ought to say, well, we've started the reregistration program and 15 years from the date of the registration, we're going to bring you back up, so that that person at least knows, you know, 15 years ahead of time.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED MALE: The ones before that were

trying to set priorities. But once the system starts, there ought to be 15 years from the date of the registration.

UNIDENTIFIED FEMALE: It seems like there's got to be something in your new computer system or one -- something you could add, that as soon as you -- granted, there's a ticker now, 15 years now it pops up again. So, I think Warren's right. Once we get the things that we've got on our plate right now in the system, it will take care of itself because as soon as you finish one, it starts a clock for 15 years.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: But --

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Remind me to --

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: But, also, too, again --

UNIDENTIFIED FEMALE: It won't go out that -- it probably will go out that far.

UNIDENTIFIED FEMALE: But going back to the quaternary ammonium compounds again, because you're talking here about hundreds, I think they're divided into

just two families and they don't -- you know, they're bridged to each other. So, if you register a new quat today, and -- but the quat family is going through reregistration or the registration review or whatever X time, then that ought to -- you know, that ought to be clearly stated at the time of the registration, you're here and this is when you'll come up again.

I mean, so that way, too, you know, you're beginning to already put some order into the process and where something belongs in the family, you know, you indicate it and you say, this is when you'll be revisited because even though that's not 15 years, why not get it on schedule, you know, I mean, as opposed to trying to --

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Yeah. I mean, it doesn't make sense to do it otherwise if the family is being addressed as a whole.

UNIDENTIFIED MALE: Are you saying that a new AI that belongs to a family that's on schedule four years from now, that we would notify the registrant of that new AI that you aren't going to have 15 years, that you're really going to be put into this group in four years,

you'll be looked at --

UNIDENTIFIED FEMALE: Right, right.

UNIDENTIFIED MALE: -- and then you'll get on the 15 years.

UNIDENTIFIED FEMALE: Right. And, I mean --

UNIDENTIFIED MALE: Sorry.

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED MALE: What about another scenario? If you're doing a new (inaudible) chemical (inaudible) say next week and it's FQPA compliant. You know, you have everything you need to satisfy current safety standards and it's bridgeable to the class of chemicals or the family, could that not bump the entire family 15 years into the future? I mean, is that too big a leap or --

UNIDENTIFIED FEMALE: No, the converse. You're doing the converse, yeah.

UNIDENTIFIED FEMALE: I think (inaudible).

UNIDENTIFIED FEMALE: Well, now, if that whole family's database was updated as a result of that new chemical, you know -- I mean, I don't know that that would happen, but again, why not, you know?

UNIDENTIFIED FEMALE: Well, actually, you still look at the oldest one in order to (inaudible). Actually, we have to look at the oldest one. If the database has been totally updated, it's going to make that review just that much easier.

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED FEMALE: So, you're still now putting it on that 15-year (inaudible) for the oldest chemical. But otherwise the oldest is going to be (inaudible).

UNIDENTIFIED FEMALE: Yeah, we'll work this out.

UNIDENTIFIED MALE: Yeah, I would say of all things that keep me up at night, EPA acting at breakneck speed ahead of schedule isn't one of the first ones. But --

(Laughter.)

UNIDENTIFIED MALE: But I do think it's worth seriously looking at moving -- you know, if you think about what decisions EPA actually made pre-FQPA, it's kind of an interesting mix of decisions. So, you know, the types of decisions that were made, whether it's a RED or not and that kind of thing.

So, I think it's going to be a little more complicated than we're maybe initially thinking to decide what goes -- even if you did a sheerly chronological list, if there was a single use that was approved, does that trigger the entire chemical, a single early use, if EPA approved a use in 1986, does that trigger review of that entire chemical, all uses and the entire class of chemicals to which it belonged? Because if that's the case, then, you know, I'm not sure you really have a schedule at that point because suddenly everything is going to be loaded up all in the same year or a couple or three years or something, if you think about it that way.

So, I think it will be useful for us to have in front of us sort of what the schedule has been in the past and inevitably, we're going to have to talk about grouping chemicals together, because otherwise it makes no sense. You'll be in the European situation where EPA is revisiting the same chemical multiple times, which isn't a very efficient use of resources.

UNIDENTIFIED MALE: Okay. Well, let's take a break. Thanks for the good discussion. I think we've got a consensus on just a lot of general principles and

we will work on creating a list and getting it to you as soon as we can, hopefully within the next week or two. If we have problems --

UNIDENTIFIED FEMALE: She said past the 25th.

(Laughter.)

UNIDENTIFIED MALE: Let's all meet back in 15 minutes.

(A brief recess was taken.)

UNIDENTIFIED FEMALE: Steve said he was going to do it tonight.

UNIDENTIFIED MALE: First thing tomorrow morning, we'll all have it.

(Laughter.)

UNIDENTIFIED FEMALE: I don't know. When --

UNIDENTIFIED MALE: Well, Cindy was going to --

UNIDENTIFIED FEMALE: What is our schedule?

UNIDENTIFIED MALE: I think I heard Cindy say she was going to do hers within about two weeks or something.

UNIDENTIFIED MALE: She said by the end of next week.

UNIDENTIFIED MALE: End of next week. Is that

doable for you?

UNIDENTIFIED FEMALE: Okay, yeah, yeah.

UNIDENTIFIED MALE: All right. I think it ought to -- try to reflect -- we talked about different options, obviously, and --

UNIDENTIFIED FEMALE: Yeah, I think there was a lot of discussion -- just try to -- you know, yeah. This is just going to be kind of an outline with maybe some comments, to the extent that we've discussed them or I can think of them, about each one of these options.

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: It's still going to be very preliminary.

UNIDENTIFIED MALE: (Inaudible) people can add to it, embellish. Okay, good. Well, I think -- I feel like -- Betty and I feel like we are ahead of schedule. Does anybody think we need more dialogue on this priority schedule at this point?

I think like that issue as well as the scope issue, it's getting the papers done, getting them out, then if there needs to be more dialogue, we can do that through, whether it's email and/or teleconference

(inaudible) teleconferences, try to wrap up those issues while we move forward on the other two issues, the early off-ramp, as some of you call it, as well as stakeholder involvement itself. That's how Betty and I see this process playing out over the summer.

Well, if there's really no more -- if there's no need to further discuss the priority schedule, then we really are ahead of schedule and let's talk about our next get-together, which we had talked about being a teleconference. A few weeks ago when we had our first one, we talked about meeting every about three weeks or so because that's about the best we could do it, recognizing people's summer schedules, vacations, work travel, so on and so forth.

I do have a calendar here in front of me for the rest of the summer.

UNIDENTIFIED FEMALE: Are we going to meet after the drafts have been issued and we've had a little time to (inaudible)?

UNIDENTIFIED MALE: Yeah, right, right. Three weeks from now would put us, I think, in the first week of August and we should have the papers drafted and

around and probably back and forth by then.

UNIDENTIFIED FEMALE: Yeah, well -- okay, we'd have the papers finished by the 25th, so then you'd be circulating them the week of the 28th.

UNIDENTIFIED MALE: I'd give it at least one more week and let things percolate a little while folks read those and react.

UNIDENTIFIED FEMALE: Another thing, is APCO the week of August 4th?

UNIDENTIFIED FEMALE: And I have meetings all week August 4th. The week of August 11th? That actually -- that's only three-and-a-half weeks.

UNIDENTIFIED FEMALE: That's something that we want to make APCO aware of, that this is going --

(End of Side A, Tape 3)

UNIDENTIFIED FEMALE: Well, I think it would be incredibly helpful to have state representation in these discussions. I think that --

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: Well, they really do have some important things to discuss from their perspective, you know, that --

UNIDENTIFIED MALE: Okay. I think the week of August 11th and the following week, the week of the 18th, I am out both of those weeks. But I don't see any reason why -- it can still move on, obviously. And then if we had it the week of the 11th, then just roughly speaking, have the next meeting, perhaps, the first week in September or the second week and then another one -- I don't want to get too backed up because we talked about -- we've got PPDC at the end of October.

Then we wanted to have another face-to-face meeting prior to that, early to mid-October, so we can pull everything together and sort of know who's -- which two or three individuals in the group would be doing the presentation to PPDC, what the recommendations are, so on and so forth. I guess that works out.

UNIDENTIFIED FEMALE: What are the PPDC dates?

UNIDENTIFIED MALE: Pardon me?

UNIDENTIFIED FEMALE: What are the PPDC dates?

UNIDENTIFIED MALE: I believe the 29th and 30th. Come in Halloween costumes. So, the week of August 11th --

UNIDENTIFIED FEMALE: This is for the

teleconference, right?

UNIDENTIFIED MALE: Teleconference, right. What we can do is send out the email to everyone a couple days and times and then you all respond and we'll find out which one works the best for the most people.

UNIDENTIFIED FEMALE: Can we try to do all of the teleconferences and the meetings? Can we, you know, schedule them all?

UNIDENTIFIED MALE: Now?

UNIDENTIFIED FEMALE: Because I think that's better to schedule them in advance. I think you'll have better attendance.

UNIDENTIFIED MALE: Okay, sure. Okay.

UNIDENTIFIED FEMALE: And participation.

UNIDENTIFIED MALE: All right. So, the week of August 11th, any particular day that's not good for a lot of people, like Mondays, for example, or Fridays? Do you want to stick with Tuesday, Wednesday, Thursday or is Monday okay?

UNIDENTIFIED MALE: Just personally, Monday is preferable for me. I've got a ton of meetings that week. Monday, Thursday.

UNIDENTIFIED MALE: Monday works generally? Okay. And let's see, do we have any West Coast people?

UNIDENTIFIED MALE: Carolyn. Carolyn and Cindy.

UNIDENTIFIED FEMALE: Well, Mountain time. They're Mountain time.

UNIDENTIFIED MALE: All right. So, we'll -- I'm trying to think, our last conference call was, I think, 2:00. Does that work? Okay, so August -- Monday, August 11th from 2:00 -- I'll get a block of time of 2:00 to 4:00.

And then September 1st is Labor Day, the 2nd, does that work?

UNIDENTIFIED MALE: Again, for a teleconference?

UNIDENTIFIED MALE: For a teleconference. Or no?

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: Wednesday.

UNIDENTIFIED FEMALE: It might be better, yeah, to put that toward the end of the week, yeah.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED FEMALE: That's right.

UNIDENTIFIED FEMALE: Wednesday is okay with me,

the 3rd.

UNIDENTIFIED MALE: So, the 3rd. So, we'll also shoot for 2:00 to 4:00. And then I guess I would suggest --

UNIDENTIFIED MALE: That's a Wednesday, right?

UNIDENTIFIED MALE: Correct.

UNIDENTIFIED FEMALE: Wednesday, yeah.

UNIDENTIFIED MALE: Correct. September 22nd, which is a Monday -- back to Monday.

UNIDENTIFIED FEMALE: That's for a meeting or still a call?

UNIDENTIFIED MALE: Teleconference.

UNIDENTIFIED MALE: That's going to be right in the middle of your meeting, Ray.

UNIDENTIFIED FEMALE: Right, that's the CLA meeting.

UNIDENTIFIED MALE: Hmm.

UNIDENTIFIED FEMALE: What would be better?

UNIDENTIFIED MALE: I don't have a calendar.

UNIDENTIFIED FEMALE: The 24th?

UNIDENTIFIED MALE: Yeah, the 24th.

UNIDENTIFIED MALE: The 24th, Wednesday. Okay.

And then October, which would be a meeting -- a group meeting face-to-face here -- the 13th is Columbus Day. That Monday is out. Again, we could go to, let's say, a 15th.

UNIDENTIFIED MALE: We've got a conflict, several of us do anyway, on the 15th.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: The 14th?

UNIDENTIFIED MALE: I can't on the 14th. The 16th works.

UNIDENTIFIED MALE: The 16th works?

UNIDENTIFIED FEMALE: What is that?

UNIDENTIFIED MALE: The 16th is fine.

UNIDENTIFIED FEMALE: Is that a Thursday?

UNIDENTIFIED FEMALE: Yeah, it's a Thursday. National Bosses Day.

UNIDENTIFIED MALE: Well, I guess we'll all be in parties that day. That would be an all-day meeting.

UNIDENTIFIED FEMALE: When is the PPDC meeting?

UNIDENTIFIED MALE: 29th and 30th, I believe, or the 30th and 31st.

UNIDENTIFIED MALE: 29th and 30th.

UNIDENTIFIED FEMALE: You can't have it on Halloween. Come in costumes.

UNIDENTIFIED MALE: Okay. And then, you know, as we have our next meeting, as this evolves and we see we need to make changes somehow for some major reason, you know, we'll do that, but try to minimize that.

So, those are the -- that's the upcoming schedule and the next steps -- all right. We already talked about Cindy's going to do a paper and send it around. (Inaudible) going to do a paper and send it around by the end of next week. EPA will do our best to pull together the lists of chemicals.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: Right.

UNIDENTIFIED FEMALE: (Inaudible) look like a slacker.

UNIDENTIFIED MALE: And if you can organize the lists right away.

UNIDENTIFIED MALE: (Inaudible) do a list. (Inaudible).

(Brief pause.)

UNIDENTIFIED MALE: Okay. Was there anything

else as far as action items, things that I missed?

(No response.)

UNIDENTIFIED MALE: Okay, moving on. Public comment. Not a whole lot. But here's an opportunity -- it's like open mic. Anyone in the public area back there want to make a comment?

(No response.)

UNIDENTIFIED MALE: Going once, twice, okay.

UNIDENTIFIED FEMALE: Can I say something? I just wanted to mention one more thing about labels. We've talked about -- the problem with inconsistent labels, labels that aren't up-to-date, et cetera, was sort of woven in and out of our conversation today and I really regret that Steve Rutz was not here for this meeting. I think that a state person really has to deal with the difficult issues of poor labels. So, I think he could have really offered a lot to us today.

I'm not convinced -- you know, I'm not trying to make an argument that the registration review should be a big label review project, but there may be things Steve would like to say. There may be recommendations that this group would want to make to the agency, not that

registration review should include addressing the label problems, but that perhaps we could make recommendations to the agency about addressing this problem in -- somewhat through registration review, but maybe through other avenues. But I think it's something that we need to talk about some more, especially when we have Steve Rutz with us.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED FEMALE: I think for registration review to be an effective way of looking at labeling, we have to have the standards for labeling in which to look at those labels against and I think we were kind of talking during the break that maybe this issue has come up repeatedly. That may be a topic -- a separate topic for the PPDC to say, what is the best way for the agency to get their, you know, hands around getting labels consistent -- I want to say user-friendly. You know, the states continually have labeling issues and maybe we just need to look at what's the best mechanism within the agency for addressing labeling issues.

UNIDENTIFIED FEMALE: Here, here.

UNIDENTIFIED MALE: Just to add a little piece

on to that, two things. We do have a process on improving labels working with states. It's a process we started maybe a year ago, year-and-a-half ago. I'm not sure I know the full name, but it's a program called State Labeling Initiative Tracking System. I think that's what it's called.

And it's a mechanism that we set up with all the states where they -- they do their state registrations looking at labels and identify something that doesn't make sense, inconsistencies or whatever we've now processed whereby they contact -- I'm not sure of the name of the people in the various divisions, but there's somebody in the registration division -- it might be Linda Arrington, I'm not sure. Somebody in the registration division, as well as the other two divisions that register products, say here's a problem, here's exactly what it is and then we go about and fix it.

I'm not involved in it, so I don't know too many of the details, I've heard from the states, as well as our own people, that it's working fairly well. Has it cured all the problems? Of course not. But there is a mechanism that we set up because of these kinds of issues

that we were hearing from states.

The second thing is I was telling some at the break, we're about ready, hopefully, to issue an updated label review manual. It's been a number of years since we had it or since we updated it. It's been through OMB and USDA review. We hope -- keeping our fingers crossed. When that is ready to go out, hopefully it will be later this month, we will then make that publicly available. It's basically an internal tool that the regulatory divisions are to use.

Again, it's guidance for our product managers and chemical review managers, but we will put it on our website, do a press release, and we're starting some discussion about having a kind of workshop as well with -- Warren and I have talked about this with various industry organizations and OPP together to go through it, sort of an educational workshop.

So, there are a couple initiatives in place that we've planned to improve things. But I will also take your message back to Anne and Jim about your concerns about the labeling and how to improve them and make them more consistent. And I agree that hearing from Steve,

he's an important player to this and (inaudible).

UNIDENTIFIED FEMALE: (Inaudible) opportunity for input into this process and -- because I know certainly the crop consultants, these are the issues we deal with daily in (inaudible).

UNIDENTIFIED MALE: Um-hum.

UNIDENTIFIED FEMALE: We probably could have some real constructive inputs into that. It's -- I know it's complicated for each product and all that, but there are some really -- there's some very simple requirements that would clear things up and make it a whole lot easier for the end user. The key questions come up all the time and it's (inaudible) environment effects.

UNIDENTIFIED MALE: That might make sense at this stage for a few key outside reviewers to look at it before it comes out on the website and then you decide that it needs some changes.

UNIDENTIFIED MALE: The way we're thinking about the label review manual, it's drafted in chapters and with the -- we can see it as a living document and as there needs to be changes for one reason or another, we then update a chapter and send it out and make it more

flexible and manageable that way, rather than having to redo the whole thing.

UNIDENTIFIED MALE: Jay, I think, too, that the electronic labels that's being run in the pilot program right now would really help in the review in establishing the base and then -- I don't know if you've seen the program or not, but basically they can, you know, with the push of a button, be able to tell what's been changed and what hasn't.

UNIDENTIFIED MALE: (Inaudible) lot of the problems. (Inaudible) educational process, but also (inaudible).

UNIDENTIFIED MALE: I think an early retirement program would probably help.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: I'm getting close to it, I think.

(Laughter.)

UNIDENTIFIED MALE: Ted Head, NuFarm.

UNIDENTIFIED FEMALE: You know, Jay, I think -- you know, it's good this program they have with the states and the states being able to -- but really I think

the states usually are looking at labels primarily from an enforcement standpoint and maybe there's some way of expanding what you're doing with the states so that other stakeholders, such as crop consultants or others -- you know, again, almost going back to the previous -- I mean, have the label coordinating group that you could just address labeling policy issues for or labeling concerns and maybe, you know, expanding upon. But I think it's just a good topic maybe for the PPDC to just say, what are some of the ways (inaudible).

UNIDENTIFIED FEMALE: As far as updating the manual, this will -- this is a web document. This is not something that I think that people are going to print out. I mean, I know other guidance documents that are on the web. You know, you might need a particular page that you'll print out, but -- so, I would encourage you to look at the mechanism for, like, issuing a press release or something or a notice or putting in what's new, you know, highlighting whatever has been changed.

UNIDENTIFIED MALE: We will.

UNIDENTIFIED FEMALE: Because, again, I think that it's really going to be basically an electronic

tool.

UNIDENTIFIED MALE: Put a date of issue on every page so you know when it's been updated.

UNIDENTIFIED MALE: Okay, meeting wrap-up. I think we've had a great day, accomplished more than I thought we would. I think it's good that both the willingness to do some more work outside of these get-togethers by crafting papers and sending them around, your continued willingness to meet throughout the summer, telephonically and in person later in October, I think you all have made a lot of positive suggestions.

I think you also understand that -- what we've -- where we've come from, where the agency and you all have come from has been very complex, taken a lot of time, worked through a lot of legal, regulatory policy, administrative, science issues on reregistration and tolerance reassessment. That continues to evolve and I'm hearing that you all want to use sort of a lessons learned to make a more efficient process for registration review, and certainly the agency does, too.

I think it's everyone's interests. We want to do it right, we want to do it thoroughly; however, that

gets defined. So, anything else? Any sort of last comments?

(No response.)

UNIDENTIFIED MALE: If not, we're adjourned early.

(The meeting was concluded.)

CERTIFICATE OF TRANSCRIPTIONIST

I, Elizabeth M. Farrell, do hereby certify that the foregoing transcription was reduced to typewriting via audiotapes provided to me; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

Elizabeth M. Farrell

ELIZABETH M. FARRELL

Transcriptionist

For The Record, Inc.
Waldorf, Maryland
(301)870-8025